MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

December 12, 2018
3:00 p.m.

Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 3:00 p.m. on December 12, 2018 via conference call. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 3:00 p.m. on December 12, 2018.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes pursuant to Section 610.021(1), (13) and (14) and section 324.001.8, RSMo. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.
***REVISED TENTATIVE AGENDA***
Missouri Board of Pharmacy
CONFERENCE CALL

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

December 12, 2018
3:00 p.m.

OPEN SESSION AGENDA

1. Call to Order: Christian Tadurs, PharmD, President

2. Roll Call

3. Approval of Minutes
   a. July 10, 2018
   b. July 11-12, 2018

4. FDA Compounding Memorandum of Understanding Response

5. Rx Cares for Missouri Updates
   a. Draft Contract
   b. Draft Emergency Rule

6. Proposed 2019 Legislation
   a. Pilot Projects
   b. Pharmacy Technician Proposal
   c. Pharmacy Practice Advancement
   d. Prescription Drug Monitoring Program (Added 12/7)

7. 3PL/Drug Outsourcer Licensing Update

8. Special Sites
   a) Conduent
   b) Lafayette Regional Health Center
   c) North Colorado Family Medicine Clinic
   d) PillarRx Consulting
   e) St. Louis VA-North County Comm. Based Outpatient Clinic
   f) St. Louis VA-St. Charles County Comm. Based Outpatient Clinic

9. Future Meeting Dates/Times

10. The Board may go into closed session at any point during the meeting and
votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (5), (7), and (14) and under Section 324.001.8, and .9 RSMo. The Board will return to open session at the conclusion of discussion on closed session items.

11. Adjournment
#3 APPROVAL OF MINUTES

- July 10, 2018
- July 11-12, 2018
- July 20, 2018
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 Vice-President Douglas Lang at approximately 8:07 a.m. on July 10, 2018. Each item in the minutes is listed in the order discussed.

**Board Members Present**
- Christian Tadrus, R.Ph., President
- Douglas R. Lang, R.Ph., Vice-President
- Barbara Bilek, PharmD., Member
- 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
- Sarah Decker, Compliance Coordinator
- Jennifer Luebbert, Administrative Coordinator

Vice-President Douglas Lang opened the strategic planning meeting at approximately 8:09 a.m.; Roll call was taken. Mr. Lang reported Christian Tadrus will be joining the meeting in the afternoon due to a flight delay and noted agenda items may be moved until after Mr. Tadrus arrives.

**Agenda Item # 1 (Executive Director Operations Report)** - Kimberly Grinston indicated a full report will be provided later in the morning. However, Mrs. Grinston provided the results of a recent electronic Board survey asking Board members to rank/prioritize strategic planning agenda items in five core areas: public protection, economic value, administrative value, licensee understanding and priority level. Mrs. Grinston reported strategic agenda items were prioritized/ranked as follows based on Board member assigned scores:
1. Review of Board Meeting Procedures (126)
2. Review of Bd. Administrative Operations (122)
3. Licensee Education/Training (122)
4. Standards Based Regulation (115)
5. Remote Product Verification (113)
6. Patient Counseling Survey (113)
7. Developing a 2019 Strategic Plan (113)
8. Board Member Development/Training (107)
9) Remote Technician Data Entry (107)
10) Quality Assurance Reporting (105)
11) Class-O Automated Dispensing System (104)
12) Well-Being Program/Addiction Education or Intervention Options (101)

Full survey results and rankings are included in Attachment A. Pamela Marshall stated many of the lower ranking items are still important and suggested the Board consider these items in the near future.

Agenda Item # 5 (Review of Board Meeting Procedures)- Kimberly Grinston presented the current staff delegation list and a proposed delegation list. Board discussion held; A motion was made by Pamela Marshall, seconded by Barbara Bilek, to approve the proposed staff delegation list for Non-Resident Discipline as identified in Attachment B. Motion passed 4:0:0:1 by roll call vote as follows:

Barbara Bilek – Yes Pamela Marshall – Yes Anita Parran – Yes
Christina Lindsay- Yes Christian Tadrus- Absent

Board discussion held on the proposed staff delegation for Criminal History; A motion was made by Christina Lindsay, seconded by Pamela Marshall, to allow staff to issue/NFA applicants with felonies that are greater than seven (7) years old with the exclusion of sexual or drug related charges. Motion passed 4:0:0:1 by roll call vote as follows:

Barbara Bilek – Yes Pamela Marshall – Yes Anita Parran – Yes
Christina Lindsay- Yes Christian Tadrus- Absent

Further discussion held; A motion was made by Christina Lindsay, seconded by Pamela Marshall, to approve the proposed staff delegation list as identified in the remainder of the Criminal History section contained in Attachment B. Motion passed 4:0:0:1 by roll call vote as follows:

Barbara Bilek – Yes Pamela Marshall – Yes Anita Parran – Yes
Christina Lindsay- Yes Christian Tadrus- Absent

Further discussion held; A motion was made by Christina Lindsay, seconded by Anita Parran, to approve the proposed staff delegation list as identified in the Complaints/Cases (NFA) section contained in Attachment B. Motion passed 4:0:0:1 by roll call vote as follows:

Barbara Bilek – Yes Pamela Marshall – Yes Anita Parran – Yes
Christina Lindsay- Yes Christian Tadrus- Absent

Board discussion held on proposed staff delegation for Complaints/Cases (Administrative Letters); Kimberly Grinston reported Christian Tadrus expressed concerns with staff issuing a Letter of Warning without full Board review. Tom Glenski indicated a compliance notice would be issued without Board review if the items listed were discovered during an inspection. A
motion was made by Pamela Marshall, seconded by Barbara Bilek, to approve the proposed staff delegation list for Letters of Warning as identified in the Complaints/Cases (Admin. Letters) section of Attachment B. Motion passed 4:0:0:1 by roll call vote as follows:

Barbara Bilek – Yes  Pamela Marshall – Yes  Anita Parran – Yes  Christina Lindsay- Yes  Christian Tadrus- Absent

A motion was made by Christina Lindsay, seconded by Anita Parran, to delegate staff authority to issue a Letter of Concern for late reporting of employee/technician discipline. Kimberly Grinston indicated the LOC recommendation was included in error and noted failure to report discipline was included in the Letter of Warning recommendations. Christina Lindsay withdrew the motion; Anita Parran withdrew the second. [See Attachment B for a full list of delegated staff authority]

Kimberly Grinston asked for additional ways to streamline the Board agenda process; Douglas Lang indicated Board members can’t adequately review lengthy addendums that are provided close to the meeting date and recommended that licensing matters be handled via e-mail ballot. Pamela Marshall agreed lengthy addendums are problematic. Christina Lindsay stated e-mail ballots are not sent on standard days and noted Board members may not know to check private e-mail accounts. Board consensus to allow seven (7) days for e-mail ballot responses and to provide notice of e-mail ballots to Board members’ public and private e-mail accounts.

Christina Lindsay and Pamela Marshall further suggested developing a process to allow Board members with expertise in a particular area to assist in developing rule language/comments prior to full Board review.

Agenda Item # 7 (Licensee Education/Training)- Board discussion held on future licensee/educational opportunities. Christina Lindsay reported she’s received positive feedback on the Board’s paper communications. Public attendees Samuel Leveritt and David Wolfrath recommended the Board send out both paper and electronic newsletters. Board consensus to pursue the following:

• Increase e-alert enrollment.
• Coordinate with MPA and MSHP to increase publication of Board projects/educational events.
• Update the Pharmacy Practice Guide and publish in August 2018. Board consensus to revise the Practice Guide annually in the future.
• Continue webinars with topics such as: recent legislation/rule changes, BNDD update, inspection violations/disciplinary concerns and hot topics.

Agenda Item # 11 (Well-Being Program)- Pamela Marshall and Douglas Lang reported the APhA School on Alcoholism and Addiction held in Utah was highly beneficial and provided excellent addiction resources and training. Pamela Marshall suggested mandating attendance at the Utah program for impaired licensees on discipline. Douglas Lang suggested asking other states about impairment tools/initiatives. Board consensus to research other state initiatives and to suggest Kansas include a discussion on Well-Being programs at the upcoming Dist. 6 Missouri Board of Pharmacy Open Minutes (Strategic Planning) July 10, 2018 Page 3 of 7
meeting. Further Board consensus to develop a list of addiction/treatment related resources for the website, including, resources on support groups such as AA and Al-Anon.

**Agenda Item # 12 (General Board Discussion Topics).** The following discussion was held:

- Pamela Marshall suggested the Board consider requiring or recommending a pharmacy quality assurance/quality improvement (QA/QI) program. Mrs. Marshall noted QA/QI can be instrumental in protecting patients and detecting/preventing errors. Douglas Lang noted several states require a QA/QI program of some sort; Barbara Bilek reported the Joint Commission and CMS already require QA/QI for hospitals. Board discussion held on the need to protect QA/QI data while still allowing Board access to needed information. Board consensus to form a sub-committee consisting of Pamela Marshall, Christian Tadrus and Kimberly Grinston to develop suggestions for adopting, implementing or encouraging QA/QI programs in Missouri.
- Kimberly Grinston asked if the Board wanted to audit all licensees for CE compliance given that CPE Monitor is now available. Douglas Lang asked if staff could be delegated authority to address CE violations without requiring full Board review. Board discussion held; Board consensus to review the 2016 CE audit results at a future meeting and then discuss possible staff delegation. Kimberly Grinston asked the Board to reconsider the $1,000 late CE fee. Board discussion held; Board consensus for staff to develop a sliding scale of late fees for future Board review.
- Barbara Bilek suggested the Board review approval of intern sites; Kimberly Grinston indicated the Board previously gave staff authority to approve licensed pharmacies and pharmacists without discipline. Board discussion held; Board consensus to discuss intern pharmacist expiration dates, approval of non-pharmacist preceptors and special site approval requirements at the October meeting.

CHRISTIAN TADRUS JOINED THE MEETING AT 1:32 P.M. AND ASSUMED CHAIR OF THE MEETING.

**Agenda Item # 3 (Standards-Based Regulation).** Alex Adams, Executive Director of the Idaho Board of Pharmacy, provided an update on Idaho’s recent move to standards based regulation in lieu of prescriptive rules. Mr. Adams provided the following information:

- Idaho’s regulatory reform was primarily focused on empowering pharmacist activities and incorporating evidence-based regulation. Generally, pharmacists are allowed to perform an activity if: (1) the activity is not prohibited by other governing law, (2) the activity is within the pharmacist’s education, skill and training and (3) the pharmacist complies with the acceptable standard of care.
- Idaho maintained detailed regulation in areas that posed the highest risk of patient harm, including, controlled substance dispensing and compounding.
- Rules and statutes were revised at the same time. The initiative would not have been successful without legislative support and the Board having fining authority to address less egregious violations.
Board consensus to hold further discussion until the July 11th open session meeting as publicly posted.

**Agenda Item # 19 (Patient Counseling Survey)**- Board discussion held on the merits of the patient counseling survey. Pamela Marshal noted the proposed survey questions were vague; Douglas Lang expressed concerns the survey would not reflect how patients prefer to be counseled and may not be applicable to all practice settings. Pamela Marshall and Christian Tadrus suggested the Board clarify the goal of the survey prior to engaging licensees. Douglas Lang questioned if the Board should focus on education in lieu of a detailed survey that may not be useful. Further Board discussion held; Board consensus to focus on ways to promote best practices and educate pharmacists and the public. Further consensus to ask Missouri’s pharmacy schools for suggestions/recommendations. Kimberly Grinston suggested the Board may be able to use funds from the Rx Cares for Missouri program for patient counseling education.

**Agenda Item # 1 (Executive Director Operations Report)**- Kimberly Grinston provided the following updates:

- The state is transitioning to Governor Parson’s administration; Agencies have been advised no immediate changes will be made to Department directors. The Governor’s office has also advised Board appointments will be made based on priority and that Board/Commissions without a quorum will likely be appointed first.
- All of the Board’s budget requests were approved this year, including, the NDI requests for inspector salary increases.
- 2018 proposed legislation is due by August 1, 2018. The Division has discussed the need to educate legislators on the value of licensing boards and the efficiencies that have been adopted.
- The Board currently has four sub-committees in operation: the Nuclear Working Group, the Sterile Compounding Sub-Committee, the Drug Distributor Advisory Committee and the Hospital Advisory Committee.
- Regina Walker will be leaving the Board on July 13th; Kim Hatfield will move from the technician desk to replace her. The office has begun cross-training to ensure continuity of operations.

The Executive Director’s report culminated with a demonstration of the Board’s updated website.

**Agenda Item # 2 (Chief Inspector Operations Report)**- Tom Glenski presented his report as included in the agenda; No novel inspection, investigation or complaint trends were noted. Mr. Glenski explained the Board’s inspection process and recent changes to the inspection program. Board members asked to consult with BNDD to ensure collaboration on inspection activities.

**Agenda Item # 4 (Review of Board Administrative Options)**- The following discussion was held:

- Kimberly Grinston indicated current facilities and equipment are adequate, however, inspectors could benefit from tablets in the field. The state IT department is still reviewing compatible tablets.
• Christian Tadrus asked about Board audio equipment; Ms. Grinston reported sound quality should improve because the office recently purchased a new speaker after consulting with the Board’s audio vendor.
• Kimberly Grinston reported staffing levels are adequate even though an additional clerical person would be helpful. Ms. Grinston stated salary is the primary impediment to recruiting and retaining qualified staff but noted the new merit reform bill may expand possibilities.
• Christian Tadrus asked if the Board needed to review office policies/procedures to ensure consistent regulation. Pamela Marshall and Douglas Lang suggested staff actions appear to be consistent but suggested cross-walking all of the Board’s policies and procedures.
• Board members asked about staff training for non-inspectors; Kimberly Grinston reported training has been provided on organizational and customer service topics in the past. Douglas Lang asked if advancement training is provided; Kimberly Grinston indicated advancement training is problematic because there are no advancement opportunities in the office.

**Agenda Item # 6 (Board Member Development)** - The following discussion was held:

• Board members suggested enhancing training for new Board members and possibly incorporating a mentoring process
• Board consensus to arrange dates for Board members to observe an inspection; Board members noted the exposure would be beneficial for members who may be unfamiliar with certain practice settings.
• Pamela Marshall and Douglas Lang recommended all Board members attend the Utah addiction training program; Christian Tadrus indicated he would like to attend in 2019.
• Christian Tadrus asked Board members if additional education was needed on electronic data and industry standards: Board consensus that additional information would be helpful via a speaker or other learning materials.

**Agenda Item # 8 (Enhancing Technology Usage/Engagement)** - The following discussion was held:

• Christian Tadrus indicated social media is still a barrier given state agencies haven’t been fully authorized to explore social media channels.
• Christian Tadrus noted Stage 1 of the website revision has been completed but suggested the website can still be more mobile friendly (e.g., larger fonts, better topic headings). Mr. Tadrus suggested exploring ways to enhance search functions and including a FAQ on the website. Board discussion held; Board consensus to research incorporating a live chat or blog function on the website.
• Christian Tadrus discussed electronic board meeting options; Jennifer Luebbert reported the Division identified a potential product but the concept was considered unworkable because all Board members would need to have Windows 10. Additionally, other Boards reported customer service and contract issues with the vendor. Douglas Lang suggested the Board consider a tool like WebEx that would
allow Board members to view each other during meetings. Board consensus to research electronic meeting options.

**MOTION TO CLOSE- 8:16 P.M.**
At 8:16 p.m., Douglas Lang made a motion, seconded by Anita Parran, that the Board go into closed session pursuant to Section 610.021(3), RSMo, for personnel reasons and that all votes pertaining to and/or resulting from this closed meeting be closed, to the extent permitted by law,. Motion passed 5:0:0:0 by roll call vote as follows:

Barbara Bilek – Yes  Pamela Marshall – Yes  Anita Parran – Yes
Christina Lindsay – Yes  Douglas Lang – Yes

**RECONVENE OPEN 8:54 P.M.**
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:54 P.M. on July 10, 2018.

THE BOARD RECESSED FOR THE EVENING AT APPROXIMATELY 8:54 P.M.

______________________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
OVERALL RANKINGS

**Review of Board Meeting Procedures**  
Enhancing Technology Usage/Engagement  
Review of Bd. Administrative Operations  
Licensee Education/Training  
Standards Based Regulation  
Remote Product Verification  
Patient Counseling Survey  
Developing a 2019 Strategic Plan  
Board Member Development/Training  
Remote Technician Data Entry  
Quality Assurance Reporting  
Class-O Automated Dispensing System  
Well-Being Program/Addiction Education or Intervention Options  

126

123

122

122

115

113

113

113

107

107

105

104

101

TOP BY CATEGORY

<table>
<thead>
<tr>
<th>Category</th>
<th>Top Priorities</th>
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| Public Protection   | • Quality Assurance Reporting  
                      • Licensee Education/Training  
                      • Review of Bd. Meeting Procedures, Remote Tech Data Entry,  
                        Remote Product Verification, Class-O, Patient Counseling  
                        Survey & Enhancing Technology (TIE) |
                      • Licensee Education/Training & Developing a 2019 Strategic Plan  
                      • Standards Based Regulation & Patient Counseling Survey |
| Administrative Value| • Review of Bd. Meeting Procedures  
                      • Review of Board Administrative Operations  
                      • Enhancing Technology Usage & Developing a 2019 Strategic Plan |
| Licensee Understanding| • Licensee Education/Training  
                        • Patient Counseling Survey  
                        • Enhancing Technology Usage/Engagement & Quality Assurance Reporting |
| Priority            | • Remote Technician Data Entry & Remote Product Verification |
Public Protection:

**Quality Assurance Reporting:** 23  
Licensee Education/Training: 22  
Review of Board Meeting Procedures: 21  
Remote Technician Data Entry: 21  
Remote Product Verification: 21  
Class-O Automated Dispensing System: 21  
Patient Counseling Survey: 21  
Enhancing Technology Usage/Engagement: 21  
Board Member Development/Training: 19  
Standards Based Regulation: 19  
Well-Being Program/Addiction Education or Intervention Options: 18  
Review of Bd. Administrative Operations: 18  
Developing a 2019 Strategic Plan: 15

Economic Value:

**Review of Board Administrative Options:** 23  
**Review of Board Meeting Procedures:** 23  
Licensee Education/Training: 22  
Developing a 2019 Strategic Plan: 22  
Standards Based Regulation: 21  
Patient Counseling Survey: 21  
Remote Product Verification: 20  
Enhancing Technology Usage/Engagement: 19  
Class-O Automated Dispensing System: 19  
Board Member Development/Training: 18  
Well-Being Program/Addiction Education or Intervention Options: 18  
Quality Assurance Reporting: 18  
Remote Technician Data Entry: 14

Administrative Value:

**Review of Board Meeting Procedures:** 24  
Review of Bd. Administrative Operations: 23  
Enhancing Technology Usage/Engagement: 21  
Developing a 2019 Strategic Plan: 21  
Board Member Development/Training: 20  
Standards Based Regulation: 18  
Licensee Education/Training: 17  
Remote Technician Data Entry: 16
Remote Product Verification: 16
Patient Counseling Survey: 15
Well-Being Program/Addiction Education or Intervention Options: 14
Class-O Automated Dispensing System: 14
Quality Assurance Reporting: 12

Licensee Understanding:

Licensee Education/Training: 24
Patient Counseling Survey: 23
Enhancing Technology Usage/Engagement: 22
Quality Assurance Reporting: 22
Standards Based Regulation: 19
Well-Being Program/Addiction Education or Intervention Options: 19
Remote Technician Data Entry: 18
Remote Product Verification: 18
Class-O Automated Dispensing System: 18
Review of Bd. Administrative Operations: 16
Developing a 2019 Strategic Plan: 16
Review of Board Meeting Procedures: 14
Board Member Development/Training: 14

Priority:

Remote Technician Data Entry: 22
Remote Product Verification: 22

Standards Based Regulation: 20
Review of Board Meeting Procedures: 20
Licensee Education/Training: 20
Review of Bd. Administrative Operations: 19
Enhancing Technology Usage/Engagement: 19
Developing a 2019 Strategic Plan: 18
Well-Being Program/Addiction Education or Intervention Options: 18
Quality Assurance Reporting: 18
Class-O Automated Dispensing System: 18
Patient Counseling Survey: 18
Board Member Development/Training: 16
** APPROVED STAFF DELEGATION **

** Delegated cases may still be referred to the full Board depending on the individual facts. **

### NON-RESIDENT DISCIPLINE

Grant staff authority to issue licenses/NFA cases with non-resident discipline (other than revocation) for:

1. CE violations
2. Incomplete/missing policies & procedures
3. Minor reporting violations (e.g., failure to report OOS discipline, employee discipline)
4. Expired drugs in inventory (small volume)
5. Allowing unlicensed technician or intern to practice (≤ 90 days)
6. Late PDMP reporting
7. Late PIC/MIC changes
8. Pharmacy billing related issues
9. Late reporting of change of location/change of ownership (≤ 6-months)
10. Non-Sterile dispensing errors related to inaccurate quantity, mislabeling or wrong patient unless serious patient harm (≤ 3 errors)
11. Late/untimely dispensing
12. Late/incomplete controlled substance inventories
13. Failure to report disciplinary action in another state
14. Discipline based on action by another state for the above grounds (stacking discipline)

### CRIMINAL HISTORY

Issue applicants/NFA cases with:

- **Felonies** less than or equal to 7 years old (excluding sexual or drug related charges)***
- **Misdemeanors** greater than seven (7) years old or no more than 2 misdemeanors related to:
  1. DWI, DUI, OWI/OUI
  2. Public Intoxication
  3. Minor in Possession
  4. Disorderly Conduct/Indecent Exposure
  5. Resisting Arrest
  6. Theft/Shoplifting
  7. Insufficient Funds/Bad Checks
  8. Criminal Harassment
  9. Assault/Battery
10. Child Support Violations
11. Child Neglect/Endangerment
12. Domestic Violence
13. Possession of Drug Paraphernalia (≤ 1 charge)
14. Contraband
15. Trespassing
16. Tampering w/ A Motor Vehicle or Airplane
17. Property Damage/Graffiti
18. Tax/Public Benefit Violations (unemployment, disability)

- No more than 1 marijuana charge that is three years old or older
- No more than 1 drug possession charge that is three years old or older
***If no recent relevant criminal history exists***

*** All investigative cases/complaints would be reviewed by the Chief Inspector before action is taken.

## COMPLAINTS/CASES (NFA)

Grant staff authority to NFA:
- Dispensing cases with no Missouri contact (pharmacy, dispensing and patient occurred outside of Missouri)
- Cases not within Bd’s jurisdiction (e.g., complaints solely against MDs/nurses or insurance company/PBM)
- Duplicate cases (complainants submitting repeat information or “appealing” Board’s decision without additional information)
- Customer service only cases (e.g., rude conduct, credit card disputes)

## COMPLAINT/CASES (Admin. Letters)

Grant staff authority to issue a Letter of Warning for (1st offenses only):
- Late/missing NOI (≤ 9 months)
- Immunizing at location not listed in protocol
- Late reporting of employee/technician discipline (≤ 9 months/LOC for ≤ 30 days)
- Missing/incomplete policies and procedures (non-sterile)
- Missing immunization protocol (≤ 6 months)
- Incomplete immunization protocol
- Failure to transfer Rx within 1 business day (≤ 10 prescriptions)
- Incorrect expiration date, prescriber, NDC, compounding date or provider in pharmacy records
- Incorrect/incomplete compounding log records
- Compounding BUD greater than ingredients
- Late PIC/MIC change notification (≤ 60 days) *would not apply to operating without a PIC
- Late CS inventories (≤ 6 months)
- Incomplete CS inventories (e.g., missing pseudoephedrine, notation when inventory was taken)
- Failure to maintain/complete CMEA self-certification
- Violation of patient confidentiality not related to an error
- Failure to report employee/technician discipline

Full Board review required for cases not listed above, including, but not limited to, cases related to:

1) Dispensing errors
2) Drug Diversion
3) Drug losses/theft
4) Sterile compounding
5) Impaired licensees/registrants
6) Working on an expired/suspended license or registration
OPEN MINUTES
Missouri Board of Pharmacy

July 11-12, 2018
Courtyard Columbia
3301 Lemone Industrial Boulevard
Columbia, 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 Christian Tadrus at approximately 8:13 a.m. on July 11, 2018. Each item in the minutes is listed in the order discussed.

Board Members Present
Christian Tadrus, R.Ph., President
Douglas R. Lang, R.Ph., Vice-President
Barbara Bilek, PharmD., Member
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
Scott Spencer, 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 Christian Tadrus opened the meeting at 8:13 a.m.; Roll call was taken.

MOTION TO CLOSE 8:14 A.M.
At 8:14 a.m., Pamela Marshall 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 § 610.021(1), (3), (5), (7), (13), (14) and (17), RSMo. Motion passed 5:0:0:0 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 at approximately 9:16 A.M.

OPEN SESSION

#A25. Approval of Minutes
- February 7, 2018

A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the open session minutes for February 7, 2018. Motion passed 5:0:0:0 by roll call vote as follows:

Barbara Bilek – Yes  Douglas Lang- Yes  Christina Lindsay- Yes
Pamela Marshall – Yes      Anita Parran – Yes

#A24. Board Approval of Non-Resident Pharmacy Inspection Entities
- Joint Commission Request
- 20 CSR 2220-2.025

DISCUSSION: Ms. Grinston reported the Joint Commission has asked to be an approved inspection entity for non-resident pharmacies as allowed under the revised rule. Board discussion held; Board consensus to request information on the Joint Commission’s inspection process, including, inspector credentials, information sharing and the deficiency response/resolution process. Further consensus to allow the Joint Commission to either meet with the Board or submit information in writing.

#A20. Committee Updates

DISCUSSION: The following reports were provided:
- **Nuclear Working Group**: Douglas Lang reported the Working Group met on February 20th; The current goal is to provide recommendations to the Board at the October meeting. Committee members are watching developments on USP Chapter 825.
- **Sterile Compounding Sub-Committee**: Mr. Lang reported several Sub-Committee conference calls have been held; The Sub-Committee is still working on a draft emergency sterile compounding rule and is working with the Nuclear Working Group to address concerns with beyond-use-dating/in-use times.
- **Drug Distributor Advisory Committee**: Christian Tadrus reported the Committee recently held a short introductory call; The next meeting will be held on July 19th.
- **Long-Term Care Working Group**: Mr. Tadrus reported the Working Group held their second meeting after a long hiatus. The general Working Group consensus is that Missouri’s long-term care regulation is flexible but needs to be updated/clarified in several key areas. Mr. TADRUS further reported discussion was held on the definition of...
a long-term care patient and noted the Board’s rules may need to be revised to accommodate non-traditional care options such as home base care models.

- **Hospital Advisory Committee:** David Wolfrath reported the Committee recently met to discuss DHSS’ revised hospital rules. The Committee will be on hiatus for the summer. Mr. Wolfrath thanked retiring Committee Member Bert McClary and commended him on his contributions to the Committee and the pharmacy profession.

### #A22. 2018 legislation Implementation

- **HB1719**

**Executive Director Summary**

DISCUSSION: Kimberly Grinston reported the Governor has signed several bills related to pharmacy practice. Ms. Grinston further reported the office will be hosting a legislative update webinar on August 9th and suggested the Board meet in the near future to discuss legislative implementation. The following additional discussion was held:

- **HB 1719:** Kimberly Grinston advised BNDD has indicated they will not be able to issue a separate controlled substance registration specifically for third-party logistic providers or drug outsourcers due to system limitations. However, 3PLs and drug outsourcers would be able to maintain their current controlled substance registrations if the Board issues a “drug distributor/3PL” license or a “drug distributor/outsourcer license.” BNDD further advised the hybrid approach would prevent lapses in registration since its licensing system is already programmed to issue a “drug distributor license.” Board discussion held; Douglas Lang suggested 3PLs may object to a hybrid license because it may cause complications when seeking licensure in other states. Christian Tadrus questioned the legal implications of delaying enforcement of HB 1719; Board members asked to consult with legal counsel prior to voting.

- **HB 1350:** Christian Tadrus indicated the bill allows the Board to receive notification from the Highway Patrol when additional criminal history exists on an applicant/licensee. Mr. Tadrus noted the bill would require licensees to be re-fingerprinted every 6 years and suggested the Board monitor development of the new program and potential licensee costs before opting in. Anita Parran asked if the Board could opt-in at a later date; Kimberly Grinston stated agencies have been advised they may opt-in at any time. Board consensus not to participate in the program at this time but to monitor future developments.

- **ShowMeVax Reporting:** Ron Fitzwater (MPA) suggested meeting with DHSS to discuss potential implementation issues; Kimberly Grinston offered to arrange a meeting with MPA, Board staff and DHSS.

- **Opioid Supply Limits:** Board discussion held on pharmacist compliance/potential liability; Kimberly Grinston and Ron Fitzwater reported the bill was not intended to place the full compliance burden on pharmacists. Douglas Lang noted pharmacists should be reminded of their corresponding responsibility. Mrs. Grinston advised she will work with BNDD to draft implementation guidance.
#A13. Standards-Based Regulation

DISCUSSION: Board discussion held on implementing standards-based regulation in Missouri. Board members expressed support for allowing pharmacists to practice at the top of their scope, however, Board members noted Idaho has a different regulatory structure, including, fining authority. Board consensus to develop a roadmap for rule/statutory changes, explore ways to gather stakeholder feedback and consult with legal counsel on implementation challenges/requirements.

#A14. 2019 Strategic Plan

DISCUSSION: Kimberly Grinston distributed her summary notes from the July 10th strategic planning meeting; Board members asked to review the notes and discuss later on the agenda.

#A21. Implementation of Rx Cares for Missouri Program

DISCUSSION: Division Financial and Budget Director Sherry Hess joined the meeting. Ms. Grinston advised she consulted with DHSS and the Missouri Department of Mental Health (DMH) on potential projects and noted $ 750,000 has been appropriated for the Rx Cares program. Ms. Grinston reported DMH originally asked the Board to fund an educational program, however, DMH received other grant funding. Ms. Grinston noted the Board previously discussed purchasing patient medication disposal bags, funding a medication return/disposal program and sponsoring a licensee/patient educational campaign.

Ms. Hess provided information regarding the state bidding process and advised the Board would need to competitively bid any contract over $ 3,000. Alternatively, Ms. Hess advised the Board may be able to participate in another state contract that provides similar services. Board discussion held; Board consensus to research costs for all proposals and discuss at a future meeting.

#A23. 2019 Legislative Proposals

DISCUSSION: The following discussion was held:
- Tony Hughes (MSHP- President Elect) indicated MSHP is working with the Missouri Hospital Association (MHA) to develop language that would allow tech-check-tech, authorize remote technician supervision and recognize pharmacists as mid-level practitioners. Mr. Hughes encouraged the Board to consider sponsoring similar legislation or supporting MHA’s proposal. Mr. Hughes noted hospital pharmacists do not dispense directly to patients. Instead, medication is dispensed by another healthcare practitioner using technology to verify the product. Sarah Willson (MHA Vice-President) supported MSHP’s recommendations.
- John Sisto (Express Scripts) and Andy Rogers expressed support for the Board’s legislative proposals, including, the pilot project proposal.
- Ron Fitzwater (MPA) indicated that stakeholders are looking at other state PDMP models/alternatives, including, a new program in Nebraska. Mr. Fitzwater suggested Board support or Board initiation of PDMP language would be beneficial.
• Board discussion held on mandatory electronic prescribing; Christian Tadrus cautioned a fiscal note may be required. Douglas Lang asked if all pharmacies are certified to meet DEA e-prescribing standards; Mr. Fitzwater stated MPA does not have affirmative data but noted many pharmacies may be. David Overfelt (Missouri Retailers Association) indicated MRA supports mandatory e-prescribing. Board consensus that e-prescribing language could not be drafted and properly vetted prior to the August 1, 2018, legislative deadline, however, the Board would support the language if filed by another party.

Board consensus to review the Board’s prior pharmacy technician proposal and the new pilot project proposal prior to the August 1, 2018 filing deadline.

#A15. Draft Rule Review
- 20 CSR 2220-2.010 (Pharmacy Operations)
- 20 CSR 2220-2.012 (Pharmacy Supervision)
- 20 CSR 2220-2.090 (Pharmacist-In-Charge)
- 20 CSR 2220-2.120 (Transfer of Prescription Information)

DISCUSSION: The following discussion was held:
- 20 CSR 2220-2.010 (Pharmacy Operations)- Recommended changes to the proposed rule are included in Attachment A; Board consensus to hold final approval of 20 CSR 2220-2.010 pending discussions on 20 CSR 2220-2.012.
- 20 CSR 2220-2.012 (Pharmacy Supervision)- Board discussion held on remote technician supervision and remote pharmacist verification of the final product. Board members questioned if a pharmacist should be “physically present” when technician activities are performed while other Board members suggested some technician functions could be adequately supervised electronically. Board members questioned if technician training and ratio requirements should be established if remote supervision is allowed. Christian Tadrus expressed concerns regarding the lack of evidence-based research to support a specific ratio. Board discussion held on tech-check-tech, Board members expressed concerns about potential errors and allowing technicians to perform a task that requires a pharmacist’s discretionary judgment. Other Board members noted data shows technology assisted verification has a statistically low error rate that is consistent for both pharmacists and technicians. No votes were made on the rule draft.
- 20 CSR 2220-2.090 (Pharmacist-in-Charge)- Tom Glenski questioned if a pharmacist-in-charge (PIC) designation was still needed given most PICs do not have authority to address compliance violations and are “in-charge” in name only. Board members expressed concerns with not having an official contact person; Barbara Bilek asked if permit holders should be required to simply designate a contact person. President Tadrus requested a brief break to consult with the Executive Director. After consultation, Kimberly Grinston advised she’s created an electronic Board member survey to help identify what remote or technology-assisted technician activities Board members would like to authorize. A meeting break was held to allow Board members to complete the survey.
20 CSR 2220-2.012 (Cont’d)- Kimberly Grinston reported the following Board responses were received to survey questions:

1. Q: Does the Board want to allow technicians to manually check and verify final prescriptions prepared by other technicians? Four (4) Board members voted yes, one (1) Board member voted no. Board members provided the following survey comments: (1) A pharmacist should still do the PV1 verification, (2) Technician verification should only be allowed if no manipulation occurs after the pharmacist verifies the filling, (3) Only technology assisted verification should be allowed, and (4) It is important to keep the pharmacist as the final checker.

2. Q: Does the Board want to allow pharmacists to electronically supervise technicians? 50% voted yes, 50% voted no. Board members provided the following survey comments: (1) Two-way access technology should be required, (2) Electronic supervision should be allowed if there are higher standards for technician training and education and (3) Rules should vary based on the practice setting.

3. Q: Does the Board want to allow technicians to verify the final product using technology? 66% voted yes; 44% voted no. Board members provided the following survey comments: (1) A pharmacist should be required to do the PV1 verification, (2) Technician verification should only be allowed if technology is used and there is no manipulation and (3) Final pharmacist verification is important.

4. Q: Does the Board want to allow technicians to perform remote data entry? Two (2) Board members voted yes, one (1) Board member voted no and three (3) Board members declined to vote but provided the following comments: (1) Data entry should only occur in the pharmacy and (2) The technician should be in a licensed pharmacy with remote or electronic supervision.

Additional Board discussion held; Barbara Bilek and Douglas Lang suggested the survey may not truly reflect Board intent given several of the questions were unclear. Mr. Lang noted Board members may be construing the underlying concepts differently and suggested more in-depth Board discussion was appropriate.

20 CSR 2220-2.120 (Transfer of Prescription Information)- Douglas Lang asked if the rule should clarify DEA’s interpretation on initial controlled substance transfers; Tom Glenski advised the DEA’s opinion may be inconsistent between regions. Christian Tadrus reported industry groups have been working with DEA to address this issue. Kimberly Grinston recommended adding controlled substance language after the DEA provides more guidance; Douglas Lang suggested educating licensee’s in the interim. Additional discussion held; Approved rule changes are incorporated in Attachment B.

A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve 20 CSR 2220-2.120 for filing as amended. Motion passed 6:0:0:0 by roll call vote:

Barbara Bilek – Yes   Douglas Lang – Yes   Christina Lindsay – Yes
Pamela Marshall – Yes   Anita Parran – Yes   Christian Tadrus – Yes

#A18. 20 CSR 2220-2.650 (Immunization by Protocol)
DISCUSSION: Kimberly Grinston reported the office is waiting for the Board of Healing Arts to file their concurrent rule and noted the Board’s final order of rulemaking needs to be filed shortly.

#A16. Remote Product Verification, Remote Data Entry, Class-O Automated Dispensing Systems

DISCUSSION: The following discussion was held:
- **20 CSR 2220-2.725 (Remote Product Verification)** - Board consensus to hold discussion on the rule pending further discussion of the proposed pharmacy supervision and technology rules.
- **Class-O Automated Dispensing System** - Tom Glenski advised this concept may not be allowed for controlled substances. Mr. Glenski asked if the Board should license the machine or the actual location; Board consensus to license the machine. Additional Board discussion held; Proposed changes are included in Attachment C. Board consensus to review proposed changes at a future meeting and to further discuss: (1) authorized machine locations, (2) stocking by non-licensed/registered staff and (3) defining “ambulatory care.”

#A17. 20 CSR 2220-2.200 (Sterile Compounding)

DISCUSSION: Board discussion held; Approved changes are incorporated in Attachment D. A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve 20 CSR 2220-2.200 for filing as amended. Motion passed 5:0:0:0 by roll call vote:

*Barbara Bilek – Yes  Douglas Lang- Yes  Christina Lindsay- Yes  Pamela Marshall – Yes  Anita Parran – Yes*

#A16. Remote Product Verification, Remote Data Entry Sites & Class-N Automated Dispensing

DISCUSSION (Cont’d): Douglas Lang asked the Board to reconsider allowing technicians to label finish prescriptions prepared by an automated filling system if there is no manipulation of the product and technology is used to verify correct label placement. Mr. Lang noted Express Scripts is using this system in other states and noted the error rate is statistically almost non-existent given the entire process is validated using technology. Christina Lindsay questioned if the allowance would essentially allow tech-check-tech and asked if the Board should consider how this approach would affect or be applicable to all practice settings. Mr. Glenski clarified the proposal would allow technology-check-tech as opposed to technician-check-technician. Barbara Bilek questioned the number of automated filling systems a pharmacist should be allowed to supervise at the same time. Board discussion held; Pamela Marshall asked to consult with legal counsel prior to making a final decision. **A motion was made by Pamela Marshall to go into closed session for legal advice.** Christian Tadrus asked to complete the remaining open items before going into closed session.

#A14. 2019 Strategic Plan (Cont’d)
DISCUSSION: Kimberly Grinston provided her strategic planning summary notes; Board discussion held. Board consensus to update the summary notes as listed in Attachment E and review final strategic recommendations on July 12th.

#A27. Election of Officers

DISCUSSION: A motion was made by Pamela Marshall, seconded by Christina Lindsay, to reappoint Christian Tadrus as President. Motion passed 5:0:0:0 by roll call vote:

- Barbara Bilek – Yes
- Douglas Lang – Yes
- Pamela Marshall – Yes
- Anita Parran – Yes
- Christina Lindsay – Yes

A motion was made by Pamela Marshall, seconded by Barbara Bilek, to reappoint Douglas Lang as Vice-President. Motion passed 5:0:0:0 by roll call vote:

- Barbara Bilek – Yes
- Douglas Lang – Yes
- Pamela Marshall – Yes
- Anita Parran – Yes
- Christina Lindsay – Yes

#A28. Future Meeting Dates/Times

DISCUSSION: Jennifer Luebbert indicated 2019 dates will need to be approved shortly; Board consensus to have staff send out a calendar with potential conflict/availability dates. Kimberly Grinston advised the Board needs to approve final legislative drafts for 2019. Board consensus to meet via conference call on July 20th from 3:00 – 4:00 p.m. to approve legislative proposals.

MOTION TO CLOSE 6:03 P.M.
At 6:03 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 § 610.021(1), (3), (5), (7), (13) and (14), 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
- Christina Lindsay – Yes

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 1:04 P.M on July 12, 2018.

#A26. Contracts for Legal Services

DISCUSSION: A motion was made by Douglas Lang, seconded by Anita Parran, to approve all legal contracts with an amendment on travel fees for TGH litigation. Motion passed 4:0:0:1 by roll call vote:

- Barbara Bilek – Yes
- Douglas Lang – Yes
- Pamela Marshall – Yes
- Anita Parran – Yes
- Christina Lindsay – Absent
#A14. 2019 Strategic Plan (Cont’d)

DISCUSSION: Board discussion held; Board consensus to adopt strategic focus goals in lieu of a full strategic planning report at this time. A motion was made by Pamela Marshall, seconded by Douglas Lang, to approve the 2019 Strategic Focus Goals as identified in Attachment F. Motion passed 4:0:0:1 by roll call vote:

Barbara Bilek – Yes  Douglas Lang- Yes  Christina Lindsay- Absent
Pamela Marshall – Yes  Anita Parran – Yes

Further consensus to review progress on focus goals at each in-person meeting.

#A16. Remote Product Verification, Remote Data Entry Sites & Class-N Automated Dispensing

DISCUSSION (Cont’d): After consultation with legal counsel, Pamela Marshall suggested considering the proposed changes to 20 CSR 2220-2.950 in conjunction with the pending remote supervision/technology-assisted verification rules. Board consensus to hold further amendment of 20 CSR 2220-2.950 as suggested; Staff indicated revised technology rules may be ready for discussion in August. Douglas Lang acknowledged the Board’s need for consistency but suggested the Board address the specific data supported request on 20 CSR 2220-2.950 instead of indefinitely delaying the revision. Pamela Marshall indicated the Board’s goal should be to ensure consistency regardless of the technology used; Christian Tadrus suggested the Board consider a standards-based approach that would be applicable to all practice models.

#A28. Future Meeting Dates/Times (Cont’d)

DISCUSSION: Christian Tadrus invited Board members and staff to attend the upcoming August NCPDP meeting in St. Louis. Board members were asked to contact Mr. Tadrus if they were interested in attending.

MOTION TO ADJOURN 1:35 P.M.

At approximately 1:35 p.m., a motion was made by Pamela Marshall, seconded by Douglas Lang, to adjourn the July 2018 meeting. Motion passed 4:0:0:1 with roll call vote as follows:

Anita Parran – yes  Christina Lindsay – absent

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KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
20 CSR 2220-2.010 Pharmacy Standards of Operation

PURPOSE: This rule establishes general operational standards for pharmacies licensed by the Board.

(1) Pharmacy Staff and Supervision. All Board licensed pharmacies must be under the supervision of a pharmacist-in-charge who has been designated with the Board and holds a current and active Missouri pharmacist license. For pharmacies located outside of Missouri, the designated pharmacist-in-charge must hold a current and active pharmacist license in the state where the pharmacy is located.

(A) In the event the pharmacist-in-charge designated with the Board changes, the pharmacy may not continue operations until a new pharmacist-in-charge is named. A change of pharmacist-in-charge application must be submitted to the Board with the applicable fee within fifteen (15) calendar days after a new pharmacist-in-charge is designated.

(B) A controlled substance inventory must be taken at or immediately prior to a pharmacist-in-charge change as required by 20 CSR 2220-2.090.

(C) All Board licensees and registrants must wear an identification badge or similar identifying article that identifies their name and title when practicing or assisting in the practice of pharmacy (e.g., pharmacist, pharmacy technician, intern pharmacist).

(2) Required Equipment. Pharmacies must be equipped with properly functioning pharmaceutical equipment for the pharmacy services performed as recognized by the latest edition of the United States Pharmacopoeia (USP) or Remington’s Pharmaceutical Sciences.

(3) Reference Materials. The following references/resources must be physically maintained or immediately accessible in electronic form at the pharmacy:

(A) A current print or electronic edition of statutes and rules governing the pharmacy’s practice, including, but not limited to, Chapters 338 and 195, RSMo, 20 CSR 2220 and, if applicable, 19 CSR 30 governing controlled substances;

(B) Generally recognized reference(s) or other peer-reviewed resource(s) that include the following items/topics:

    1. All drugs approved by the United States Federal Drug Administration (FDA); and
2. Pharmacology of drugs;

3. Dosages and clinical effects of drugs; and

4. Patient information and counseling.

(4) General Standards of Operation. Pharmacies shall ensure pharmacy services are accurately and safely provided and must be operated in compliance with applicable state and federal drug and controlled substance laws. Except as otherwise provided by law or Board rule, pharmacies must ensure:

(A) All Missouri and federal pharmacy licenses, permits or registrations are current and accurate, including the pharmacy’s name, permit classification(s) and address;

(B) Individuals practicing or assisting in the practice of pharmacy are appropriately licensed or registered with the Board and are appropriately trained for the duties performed;

(C) All pharmacy, pharmacist, intern pharmacists and pharmacy technician licenses/registrations are conspicuously posted. Individual licenses/registrations must have a photo attached that is not smaller than two by two inches (2” x 2”). Alternatively, licenses and registrations with the required photo may be maintained in a central location within the pharmacy, provided the licenses/registrations are immediately retrievable during an inspection or available to the public if requested;

(E) Medication and drug-related devices are properly and accurately prepared, packaged, dispensed, distributed and labeled under clean, and when required, aseptic conditions. Staff required to touch individual dosage units (e.g., tablets, capsules, etc.) must wear disposable gloves;

(F) The pharmacy is maintained in a clean and sanitary condition and trash is disposed of in a timely manner. Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law; and

(G) Appropriate sewage disposal and a hot and cold water supply are available within the pharmacy, except as otherwise provided by the Board. The required water supply may not be located in a bathroom; and

(H) The pharmacy is free from insects, vermin and animals of any kind, except for service animals as defined by the Americans with Disabilities Act (ADA).
(5) Drug Storage. Drugs must be properly stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the FDA approved drug product labeling or the United States Pharmacopeia (USP).

(A) Temperatures in drug storage areas must be recorded and reviewed at least once each day the pharmacy is in operation. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that alerts a pharmacist when temperatures are outside of the required range and provides the amount of variance.

(B) No outdated, misbranded or adulterated drugs or devices may be dispensed or maintained within the pharmacy’s active inventory, including prescription and related nonprescription items. Outdated, misbranded or adulterated medication and medication for personal employee use must be quarantined in an area that is clearly identified and physically separate from medication maintained for dispensing, distribution or other pharmacy use. Drugs for the personal use of pharmacy staff or personnel must be labeled in accordance with section 338.059, RSMo, or as otherwise required by law.

(C) Food and beverage items that are not in their original, sealed manufacturer packaging must be stored separately from medication and medication-related devices. Open food or beverages used in compounding or intended for patient use with medication may be stored in the same area as drugs and drug-related devices as long as the items are separated from other inventory and sanitary conditions are maintained at all times.

(D) Medication may not be stored on the floor.

(E) Appropriate lighting, ventilation and humidity must be maintained in areas where drugs are stored and dispensed.

(6) Security. Adequate security and locking mechanisms must be maintained to prevent unauthorized pharmacy access and to ensure the safety and integrity of drugs and confidential records. Pharmacy traffic must be restricted to authorized persons so that proper control over drugs and confidential records can be maintained at all times.
(A) If the pharmacy is located in a facility that is accessible to the public and the pharmacy’s hours of operation are different from those of the remainder of the facility, ceilings and walls must be constructed of a substantial material so that the pharmacy permit area is separate and distinct from the remainder of the facility. Drop down ceilings or other openings that would allow unauthorized access into the pharmacy are not allowed.

(B) Pharmacies dispensing or stocking controlled substances must comply with all federal and state controlled substance security requirements.

(C) In addition to the other requirements of this subsection, a Class-I pharmacy within a residence must be located in a physically separate room that has a door with a suitable lock. Patients are not allowed in a Class-I pharmacy located within a residence. Other than a Class-I pharmacy, no pharmacy permit will be issued to any location that is located in a residence regardless of zoning.

(7) Record Keeping. Pharmacy records must be accurately maintained in compliance with applicable state and federal law. Records required by Chapters 195 and 338, RSMo or divisions 20 CSR 2220 and 19 CSR 30 shall be available for inspection, photographing or duplication by a Board representative. Unless otherwise provided by law, records required by Chapter 338 or 20 CSR 2220 that do not have a specified retention time must be kept for two (2) years and readily retrievable at the request of the Board or the Board’s authorized designee.

(A) Each pharmacy shall designate either a primary manual or electronic record keeping system which will be used to record the dispensing of all prescriptions and medication orders. Poison sales may be recorded in a separate manual log. Except as otherwise authorized or required by law, at least three (3) separate files of prescriptions/medication orders must be maintained:

1. A separate file for Schedule I and II controlled substances;
2. A separate file for Schedules III, IV and V controlled substances; and
3. A separate file(s) for all other prescriptions/medication orders.

(B) Distribution records. Unless otherwise authorized by law or the Board, pharmacies shall maintain inventories and records of all legend drugs received and distributed that include:

1. The date of the transaction/distribution;
2. Product name, strength and quantity;
3. The names of the parties;
4. The sender’s address or, for drugs distributed by the pharmacy, the receiver’s address; and

5. Any other information required by state or federal law.

(C) A pharmacist shall not fill or refill any prescription or medication order which was issued more than one (1) year before being presented for dispensing.

(8) Offsite storage. Medication or patient records may be maintained at a facility located at a separate address or premises from the pharmacy provided the facility is registered with the Board prior to use. Registration notices must be submitted on a form approved by the Board and include the address of the facility and hours of operation (if applicable).

(A) Adequate security and storage conditions must be maintained at these facilities to guarantee the security and integrity of records, medication and drug-related devices. At a minimum, registered storage facilities must maintain a functioning alarm system. Any breach in security must be documented and reported to the Board electronically or in writing within fifteen (15) days of the breach.

(B) Storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and will be subject to inspection by the board pursuant to section 338.150, RSMo.

(C) No record less than two (2) years old may be stored offsite. Patient records stored at an offsite facility must be retrievable within two (2) business days of a request from the board or its authorized designees.

(D) No fee will be charged by the board for registering a storage facility under this subsection.

(9) Mandatory Reporting. Pharmacies must notify the board in writing or electronically within fifteen (15) days of any final disciplinary action taken against a pharmacist, intern pharmacist or pharmacy technician for conduct that might have led to disciplinary action under § 338.055, RSMo, or resignation of a licensee/registrant in lieu of such final disciplinary action. The notification must include:

(A) The pharmacy’s name and permit number;

(B) Name of person making the notification;

(C) The licensee’s or registrant’s name and license/registration number;
(D) Date of action;
(E) Reason for action; and
(F) Any additional information required by law.

(10) Drug samples shall not be maintained in or dispensed by pharmacies, except as otherwise authorized by state and federal law, including, but not limited to, 21 U.S.C. section 353 and the federal Prescription Drug Marketing Act of 1987.

(11) A home health or hospice agency licensed or certified according to Chapter 197, RSMo, or any licensed nurses of such agency, may possess drugs in the usual course of business of such agency without being licensed as a pharmacist or a pharmacy.

(A) The following prescription drugs may be possessed by a home health or hospice agency identified in this section without a pharmacy license or permit:

1. Injectable dosage forms of sodium chloride and water;
2. Irrigation dosage forms of sodium chloride and water;
3. Injectable dosage forms of heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;
4. Injectable dosage forms of diphenhydramine, epinephrine and methylprednisolone;
5. Vaccines; and
6. Tuberculin test material.

(B) The agency shall have policies and procedures that address at least the following:

1. Specific drugs authorized to be possessed by the agency and the nurse;
2. Indications for use of the drugs possessed;
3. Receiving orders from an authorized prescriber for drug administration;
4. Leaving drugs with the patient for routine care procedures;
5. Conditions for storing and transporting drugs by the agency and nurse; and
6. Quantity of drugs possessed by the agency and nurse.

(C) The nurse must have authorization from an authorized prescriber, such as an individual patient order, protocol or standing order, to administer the drugs.
(D) Up to a two (2)-week supply of sodium chloride, water, and heparin may be left with the patient provided the patient or the patient’s representative has been instructed verbally or in writing on how to perform the procedure. Drugs left with the patient shall be labeled with instructions for use. A record shall be made of all drugs left with the patient in the patient’s medical record. Drugs left with the patient may not be returned to the agency.

(E) Drugs may be stored at the agency or transported by the nurse, and shall be stored or transported at all times in accordance with the manufacturer’s storage requirements. Except as otherwise authorized by section (5)(C) of this rule, refrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

(F) All drugs must be received from a licensed pharmacy or drug distributor. The quantity of drugs possessed by an agency shall be limited to the amount necessary to meet the needs of the agency’s patient population for two (2) weeks.

(12) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy that an employee, has violated pharmacy law or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

(13) Exemptions. At its discretion, the Board may grant an exemption to the facility requirements of this rule for a time period designated by the Board if such exemption is not contrary to law and the exemption will provide equal or greater protection of the public safety, health or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length and proposed procedures or safeguards for protecting the public safety, health or welfare if the exemption is approved.
AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and sections 338.010 and
338.210, RSMo Supp. 2007. * This rule originally filed as 4 CSR 220-2.010. Original rule filed
Jan. 10, 1976. Amended: Filed May 21, 1979, effective Nov. 12, 1979. Amended: Filed April 14,
Filed Nov. 4, 1985, effective March 13, 1986. Amended: Filed Dec. 15, 1987, effective April 28,

20 CSR 2220-2.120 Transfer of Prescription or Medication Order Information for the Purpose of Refill

PURPOSE: This rule defines record keeping required for transfer of prescription or medication order information for the purpose of refill.

(1) Prescription information shall be transferred for the purposes of refill between licensed pharmacies, provided the prescription information to be transferred meets all of the following criteria:

A. The prescription information indicates authorization by the prescriber for refilling;
B. The drug on the prescription information is not a Schedule II controlled substance;
C. The number of lawfully allowable refills has not been exceeded or the maximum allowable time limit has not been exceeded;

(A) The prescription, medication order and/or refills were authorized by the prescriber;
(B) The prescription or medication order and/or refills have not exceeded the maximum allowable time limit;
(C) If refills are involved, the number of lawfully allowable refills has not been exceeded;

(D) If the transfer involves a controlled substance, all information must be transferred directly between two (2) licensed pharmacists and comply with all state and federal controlled substance laws and regulations; and

(E) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one (1)-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) When a prescription on record is transferred, the following record keeping is required when a prescription, medication order or refill is transferred:

A. The prescription record at the transferring pharmacy shall show all of the following:

1. The word void must appear on the face of the invalidated prescription for pharmacies using a manual recordkeeping system. For pharmacies using an electronic data processing system, the prescription or medical order must be immediately promptly voided within the electronic system when the prescription is transferred;

2. The prescription record shall provide the name and location of the pharmacy to which it was transferred, the date of transfer and the identity of the persons transferring pharmacist and receiving information; and
3. If the transfer involves a controlled substance, the receiving pharmacy’s address and Drug Enforcement Administration (DEA) registration number of the pharmacy to which it was transferred and the full name of the pharmacist(s) transferring and receiving the prescription information must be recorded.

4. If the transfer involves information for a prescription or medication order that has never been dispensed, the transferring pharmacy must maintain a hard copy or image of the original prescription or medication order.

(B) The prescription record at the receiving pharmacy shall show all of the following, in addition to all other lawfully required information of an original prescription:

1. The prescription record is a transferred prescription record from another licensed location.
2. An indication that the prescription or medication order is a transfer;
3. Date of original issuance;
4. Date of original filling, if different from original issuance date;
5. Original number of refills authorized on the original prescription;
6. Number of refills originally authorized and the number of remaining authorized refills;
7. Date of last refill;
8. Prescription label number or other unique identifier;
9. Identity of licensed pharmacy from which the record was transferred.
10. The identity of the transferring pharmacist provided that pharmacies that share the same database and are under the same ownership may, instead of transferring prescriptions directly between two (2) pharmacists, transfer a prescription electronically by generating a computer-based report at the transferring pharmacy of any prescriptions that have been transferred out. This record shall be readily retrievable to the transferring pharmacy and board representatives and comply with all of the requirements of this rule, except that the requirement to document pharmacist identity shall not be required unless otherwise required by federal law.

(C) A computerized transfer of prescription information between licensed pharmacies for the purpose of refill shall meet all the requirements stated in sections (1) and (2) of this rule.
(C) An electronic transfer of prescription or medication order between licensed pharmacy must meet all of the requirements of this rule. However, pharmacies that share the same electronic database and are under the same ownership are not required to record the identities of the persons receiving and transferring non-controlled information.

(D) A Class-C Long Term Care pharmacy may transfer a non-controlled prescription or medical order to a second pharmacy for the purpose of the initial dispensing of up to a 72-hour medication supply to a long-term care facility resident without voiding the remaining prescription. The transferring pharmacy must deduct this amount from the remaining prescription or medical order but is not required to void it.

(3) A pharmacy shall receiving a transfer request from a patient or another pharmacy must complete the transfer within one (1) business day of receiving the request.


Class-O: Automated Dispensing System

20 CSR 2220-2.925

(1) Definitions.

(A) “Automated Dispensing System”: An automated system that is used to dispense medication to patients pursuant to a patient-specific prescription or patient-specific medication order using an electronic verification system. An automated dispensing system does not include an automated system used for compounding medication or an automated filling system governed by 20 CSR 2220-2.950.

(B) “Class O: Automated Dispensing System (Ambulatory Care)”: An automated dispensing system used to dispense medication directly to the public pursuant to a patient-specific prescription or patient-specific medication order.

(C) “Electronic Verification System”: An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated dispensing system.

(D) “Supervising Pharmacy”: A Missouri licensed pharmacy that is responsible for operating a Class-O automated dispensing system.

(2) Licensing- Class-O automated dispensing systems must be operated by a supervising pharmacy that is physically located in this state. Applications for a Class-O pharmacy permit must be submitted by the supervising pharmacy with the applicable fee. To be eligible for licensure, the Class-O automated dispensing system must be physically located in Missouri, pass a Board inspection and comply with the provisions of this rule. The same pharmacist-in-charge must be designated for both the supervising pharmacy and the Class-O automated dispensing system.

(3) Class-O automated dispensing systems must be operated in a manner that does not endanger public health or safety and in compliance with applicable state and federal law, including, but not limited to, all applicable controlled substance laws. The supervising pharmacy is responsible for all operations of the automated dispensing system, including, ensuring medication is accurately dispensed. Disciplinary action may be taken against the Class-O’s permit and the supervising pharmacy for non-compliance.

(A) A sign must be posted at the Class-O automated dispensing system site that is easily visible to the public informing the public that the automated dispensing system is operated by the supervising pharmacy. The sign must clearly identify the supervising pharmacy’s name, address and a toll-free telephone number for contacting the supervising pharmacy. A pharmacist must be accessible at all times the system is in operation to respond to inquiries or requests.
(B) Adequate space and equipment must be available to confidentially counsel patients. If a pharmacist is not present on-site, two-way video and audio technology must be available that allows the pharmacist and patient to both see and communicate with each other. An easily readable sign must be posted on the automated dispensing system that is viewable by the public informing patients that a pharmacist will provide counseling via the video/audio system on request. The sign must include clear instructions for requesting counseling.

(C) The Class-O automated dispensing system and the supervising pharmacy must share a common database or allow access to each other’s prescription record-keeping system. The shared system or database must allow real-time, online access to the patient’s complete profile by both the supervising pharmacy and the automated dispensing system.

(D) Prescriptions/medication orders dispensed from or entered at a Class-O automated dispensing system must be distinguishable in some manner from those filled or entered at the supervising pharmacy.

(E) Patient drug containers must be labeled in accordance with section 338.059, RSMo. Labels shall contain both the name, address and phone number of the supervising pharmacy and the Class-O automated dispensing site. [Labels must contain the name and address of the Class-O automated dispensing site and the name and contact telephone number for the supervising pharmacy.]

(4) Security. Adequate security and supervision must be maintained at all times to prevent unauthorized access or use of the automated dispensing system and to prevent medication theft or diversion.

(A) An alarm mechanism must be maintained that alerts the supervising pharmacy in the event of a security breach or unauthorized access to the ADS.

(B) Confidential records must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information. The supervising pharmacy must ensure secure data access and storage.

(C) A perpetual inventory must be maintained for each ADS that stocks controlled substances.

(D) Any security breach of the ADS must be documented and reported to the board in writing within seven (7) days of the breach.

(5) Supervision. A Class-O automated dispensing system must be supervised at all times the system is in operation by a Missouri licensed pharmacist that is physical present at the Class-O site or via an electronic system that allows the pharmacist to adequately view and supervise all Class-O activities. The supervising pharmacist must be able to terminate or suspend dispensing from the automated dispensing system if deemed necessary or appropriate.

(A) If an electronic system is used, the supervising pharmacist must maintain constant visual and two-way audio communication with the system. Medication may not be dispensed if the required video and audio links are not fully functioning.
(B) A pharmacist may not supervise more than three (3) automated dispensing systems at a time. However, the Board may grant an exemption to the supervision limit for a designated time period if the increased supervision can be adequately performed in a manner that protects the public. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length and proposed procedures or safeguards for protecting the public health, safety or welfare if the exemption is approved.

(C) Pharmacist supervision of an automated dispensing system may not be delegated to an intern pharmacist. The identity of the supervising pharmacist must be maintained in the supervising pharmacy’s records.

(6) Automated Dispensing System Requirements. Automated dispensing systems must be maintained in good working order. To ensure adequate functioning, the supervising pharmacist must maintain full operational control over an ADS whenever the system is in operation. Positive identification of recipients must be made before medication is delivered to the patient.

(A) Prior to initial operation, the system must be tested by a properly qualified pharmacy designee to ensure the system is functioning properly. Testing to measure the effectiveness and accuracy of the system must be conducted monthly. Additional testing must be performed if any modification to the ADS occurs that changes or alters the dispensing or electronic verification process. Testing dates and results must be documented in the pharmacy’s system.

(B) The supervising pharmacy must maintain separate and readily retrievable records of all transactions and prescriptions/medication orders processed by each Class-O automated dispensing system and written records of all medication stocked in or discarded from the ADS.

(C) An ADS may be stocked by an intern pharmacist, pharmacy technician or an individual acting on behalf of a Missouri licensed drug distributor when a pharmacist is not present, if an electronic verification system is used to ensure medication and prepackaged containers/cartridges are correctly stocked in the system. A pharmacist must ensure either physically or through an electronic verification system that medication has been accurately and correctly stocked. The supervising pharmacy must maintain written documentation of the date when medication is stocked/removed, the identity of individuals stocking or restocking the system and the pharmacist responsible for checking the accuracy of medication stocked.

(D) Pharmacist verification of the final product and label may be satisfied if:

1. The entire dispensing process is fully automated from the time the process is initiated until a completed and properly labeled medication container is produced that is ready for dispensing. Required labels must be affixed to the container prior to release of the medication from the ADS;

2. A pharmacist reviews and verifies the prescription or medication order and the patient/medication information used to initiate the dispensing process prior to dispensing; and

3. An electronic verification system is used to verify the correct medication and medication strength, dosage form and quantity have been dispensed.
(E) Return to stock medication may [only] be returned to the supervising pharmacy and reused as authorized by 20 CSR 2220-3.040 or 20 CSR 2220-2.145 governing multi-med dispensing.

(F) The supervising pharmacy must establish a quality assurance program to monitor the use and performance of the ADS. The following documentation must be maintained by the supervising pharmacy for a minimum of two (2) years:

1. Any security breach or unauthorized use of the ADS; and
2. Any failure of the system to dispense medication correctly and any repairs/corrective action to remedy the failure.

(7) Policies and Procedures. The supervising pharmacy must have current, accurate and written policies and procedures governing all aspects of operation of a Class-O automated dispensing system. At a minimum, policies and procedures must include:

(A) Specific and measurable standards for ensuring accuracy and safety;
(B) ADS access and security procedures/requirements;
(C) ADS stocking/restocking procedures;
(D) Procedures for maintaining and testing the ADS, including, recovery procedures;
(D) Drug security and control; and
(F) Staff education and training.

(8) Records. Except as otherwise provided by this rule or other applicable law, all records required by this rule must be maintained by the supervising pharmacy for a minimum of two (2) years and readily retrievable on request of the Board or a Board authorized designee.
EMERGENCY AMENDMENT

20 CSR 2220-2.200 Sterile Pharmaceuticals. The board is amending sections (9) and (20) of the rule.

(9) Aseptic Technique and Preparation. Appropriate quality control methods shall be maintained over compounding methods at all times to ensure proper aseptic technique.

(D) Single-dose vials/containers and pharmacy bulk vial/containers exposed to ISO Class 5 or cleaner air may be used in compounding until the assigned in-use time which shall not exceed six (6) hours after initial needle puncture, unless otherwise specified by the manufacturer. Opened single-dose ampules shall not be stored for any time period. The in-use time must be placed on the vial/container. For multiple-dose vials/containers with no antimicrobial preservative used in the preparation of radiopharmaceuticals whose beyond-use dates are twenty-four (24) hours or less, the in-use time shall not exceed twenty-four (24) hours.

[(20) Remedial Investigations: A remedial investigation shall be required if: 1) any sampling or testing required by this rule demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling/testing and/or 2) if a highly pathogenic microorganism is detected in any preparation or ISO classified area (e.g., Gram-negative rods, coagulase positive staphylococcus, molds, fungus, or yeasts).

(A) CSPs and any ingredients used within the compounding process that are part of the remedial investigation shall be quarantined until the results of the investigation are known. All affected areas shall be resampled to ensure a suitable state of microbial control as part of the remedial investigation. If a highly pathogenic microorganism is detected, or if the CFU count exceeds USP 797 action levels in any ISO-5 or ISO-7 classified area, no further compounding shall be performed until resampling shows a suitable state of microbial control. The pharmacy shall ensure that no misbranded, contaminated, or adulterated CSP is administered or dispensed for patient use.

(B) The pharmacy shall notify the board in writing within seven (7) days if any preparation or environmental monitoring/testing detects a highly pathogenic microorganism, regardless of CFU count.]

(20) Remedial Investigations: A remedial investigation shall be required if any environmental monitoring sample demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling. A remedial investigation shall include resampling of all affected areas to ensure a suitable
state of microbial control. CSPs and any ingredients used within the compounding process that are part of the remedial investigation shall be quarantined until the results of the investigation are known. The pharmacy shall ensure that no misbranded, contaminated, or adulterated CSP is administered or dispensed for patient use.

(A) If an environmental monitoring sample taken from an ISO-5 classified area exceeds USP 797 action levels, the pharmacy must cease compounding in the affected ISO classified area until resampling shows a suitable state of microbial control has been achieved in the affected area. However, a pharmacy may continue to compound during the remedial investigation if:

1. The affected ISO classified area is cleaned and disinfected by using a germicidal cleaning agent and a sporicidal agent followed by sterile alcohol;
2. The beyond-use date assigned to all preparations is no greater than twelve (12) hours, and;
3. The affected ISO classified area is resampled under dynamic conditions. If the resampling exceeds USP Chapter 797 action levels, compounding must cease until resampling shows a suitable state of microbial control has been achieved in the affected area, unless otherwise authorized by the board or board’s authorized designee to continue compounding upon a showing the facility can be operated in a manner not to endanger the public safety.

(B) If an environmental monitoring sample taken from an ISO-7 classified buffer area exceeds USP 797 action levels, the pharmacy must cease compounding in the affected ISO classified buffer area until resampling shows a suitable state of microbial control has been achieved in the affected area. However, a pharmacy may continue to compound during the remedial investigation if:

1. The affected ISO classified area is cleaned and disinfected by using a germicidal cleaning agent and a sporicidal agent;
2. The beyond-use date assigned to Risk Level 1 preparations is not greater than twenty-four (24) hours or, for Risk level 2 and 3 preparations, no greater than twelve (12) hours, and;
3. The affected ISO classified area is resampled under dynamic conditions. If two (2) consecutive resamplings exceed USP 797 action levels, compounding must cease until resampling shows a suitable state of microbial control has been achieved in the affected area, unless otherwise authorized by the board or board’s authorized designee to continue compounding upon a showing the facility can be operated in a manner not to endanger the public health or safety.

(C) The pharmacy shall notify the board in writing within three (3) days of any environmental monitoring sample collected as part of a remedial investigation that exceeds USP 797 action levels.

## FY 2019 BOARD STRATEGIC GOALS

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<tr>
<th>Licensee Education &amp; Training</th>
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<td>2. Increase subscribers to the Board’s electronic alerts &amp; newsletters. Explore ways to incorporate subscribing as part of the initial application and renewal process.</td>
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<td>8. Develop draft rule language that establishes tiered late continuing education fees based on the violation. Educate licensees on continuing education options and requirements.</td>
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| Well-Being Program | 1) Create online resource center containing Missouri treatment resources |
2) Research well-being programs in neighboring states to identify collaboration opportunities
3) Identify alternative treatment and counseling opportunities that could be provided by the Board
4) Have Board members attend the APhA impairment training program in Utah. Review incorporating attendance in impairment related Board disciplinary orders.
5) Explore opportunities to discuss state well-being initiatives at the NABP District 6 meeting.

Quality Assurance

1) Establish a Board sub-committee to research and make recommendations on ways to incorporate and promote effective continued quality improvement and Just Culture measures in pharmacy. The Sub-Committee’s review should include other state initiatives, recommendations from the Board’s 2015 Patient Safety Committee and other evidence-based materials/studies deemed appropriate.
2) Provide Just Culture or equivalent licensee education.

Board Meeting Procedures

Continue to identify ways to enhance and streamline Board meeting procedures. The following recommendations were made:
- Implement recommended staff delegation list with Board approved modifications.
- Limit the size of agenda addendums to allow sufficient time for review. Establish addendum cutoff dates.
- Research providing Board member electronic equipment to enhance Board agenda review, including, providing Board member laptops or tablets
- Explore alternative electronic meeting options such as WebEx
- Send e-mail ballots on a designated day of the week and allow seven (7) days to respond. Notify Bd members of e-
| Board Administrative Operations | • Continue to identify and provide Board inspector and staff training opportunities.  
• Increase employee cross-training  
• Continue to review and update Board internal policies and procedures  
• Discuss/develop employee succession plan  
• Research authorized online recruitment options and resources. |
| Patient Counseling | • Develop and implement a patient counseling educational campaign for both pharmacists and patients that would:  
1) Increase pharmacy awareness of effective ways to offer and provide counseling  
2) Increase patient awareness of their right to request counseling and  
3) Promote better pharmacist-patient communication  
• Promote patient counseling education campaign as part of American Pharmacists Month in October. |
| Board Member Development | • Research and provide Board member training on industry changes/topics that may impact practice. Training may include written materials or speaker presentations during Board meetings. |
| Standards-Based Regulation | • Develop and implement a roadmap for incorporating a standards-based regulatory approach that would allow pharmacists to maximize their scope of practice  
• Work with legal counsel to identify required statutory changes and regulatory opportunities/challenges  
• Gather licensee/stakeholder feedback |
## FY 2019 BOARD STRATEGIC FOCUS PLAN

| Licensee Education & Training | Continue to enhance licensee education, training & outreach:  
1. Update the Missouri Practice Guide by August 28, 2018, and annually thereafter. Provide complimentary copies to each Missouri pharmacy every two (2) years.  
2. Increase subscribers to the Board’s electronic alerts & newsletters. Explore ways to incorporate subscribing as part of the initial application and renewal process.  
3. Continue current compliance webinars. Recommended future topics include inspection violations, top compliance issues/trends and BNDD updates.  
4. Increase print and electronic licensee communications, including, mailing of Board newsletters and informational materials.  
5. Provide information on Board educational materials on initial licensure.  
6. Collaborate with Missouri pharmacy related associations to promote/advertise Board activities and educational opportunities via their membership communication tools.  
7. Provide additional online training material within current staff capability  
8. Develop draft rule language that establishes tiered late continuing education fees based on the violation. Educate licensees on continuing education options and requirements.  
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| 1) Establish a Board sub-committee to research and make recommendations on ways to incorporate and promote effective continued quality improvement and Just Culture measures in pharmacy. The Sub-Committee’s review should include other state initiatives, recommendations from the Board’s 2015 Patient Safety Committee and other evidence-based materials/studies deemed appropriate.  
2) Provide Just Culture or equivalent licensee education. | Continue to identify ways to enhance and streamline Board meeting procedures. The following recommendations were made:  
- Implement recommended staff delegation list with Board approved modifications.  
- Limit the size of agenda addendums to allow sufficient time for review. Establish addendum cutoff dates.  
- Research providing Board member electronic equipment to enhance Board agenda review, including, providing Board member laptops or tablets  
- Explore alternative electronic meeting options such as WebEx  
- Send e-mail ballots on a designated day of the week and allow seven (7) days to respond. Notify Bd |
| **Board Administrative Operations** | members of e-mail ballots at both their public and private e-mail addresses.  
- Review agenda procedures in October after implementation of expanded delegation authority. |
| **Board Administrative Operations** | • Continue to identify and provide Board inspector and staff training opportunities.  
- Increase employee cross-training  
- Continue to review and update Board internal policies and procedures  
- Discuss/develop employee succession plan  
- Research authorized online recruitment options and resources. |
| **Patient Counseling** | • Develop and implement a patient counseling educational campaign for both pharmacists and patients that would:  
1) Increase pharmacy awareness of effective ways to offer and provide counseling  
2) Increase patient awareness of their right to request counseling and  
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- Promote patient counseling education campaign as part of American Pharmacists Month in October. |
| **Board Member Development** | • Research and provide Board member training on industry changes/topics that may impact practice. Training may include written materials or speaker presentations during Board meetings. |
| **Standards-Based Regulation** | • Develop and implement a roadmap for incorporating a standards-based regulatory approach that would allow pharmacists to maximize their scope of practice  
- Work with legal counsel to identify required statutory changes and regulatory opportunities/challenges  
- Gather licensee/stakeholder feedback |
The Missouri Board of Pharmacy met in open session via conference call during the times and dates stated in the following minutes. Each item in the minutes is listed in the order discussed.

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

**Board Members Absent**
Anita Parran, Public Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Jennifer Luebbert, Administrative Coordinator
Sarah Decker, Compliance Coordinator

**Others Present**
Curtis Thompson, General Counsel
Ron Fitzwater (Missouri Pharmacy Association)

PRESIDENT TADRUS CALLED THE MEETING TO ORDER AT 3:01 P.M. AND ROLL CALL WAS TAKEN.

**#A3. Special Sites**
- Community Partnership of the Ozarks
- Nelson Mandela Metropolitan University
- SSP University of AZ College of Pharmacy

**DISCUSSION:** Tom Glenski recommended approval of the special sites listed with the exception of Nelson Mandela Metropolitan University because additional preceptor information is needed. Barbara Bilek questioned the value of the Community Partnership site for pharmacy students and indicated students may be training others without sufficient oversight. Douglas Lang also expressed concerns with the proposed student activities without pharmacist supervision. Pamela Marshall noted part of the Community Partnership curriculum would be applicable to the opioid crisis. Board discussion held; **A motion was made by Pamela Marshall to approve the special sites/preceptors listed for 500 hours with the exception of Nelson Mandela Metropolitan University.** Douglas Lang and Barbara Bilek asked if
Community Partnership and the SSP University of Arizona site should be limited to 200 hours given they are listed as 4-5 week rotations. Kimberly Grinston stated the rule gives the Board flexibility and doesn’t require approval for 500 hours. The motion died for lack of a second.

A motion was made by Barbara Bilek, seconded by Douglas Lang, to: (1) approve the SSP University of Arizona site for 200 hours per student per year, (2) deny approval of Community Partnership of the Ozarks and (3) hold approval of Nelson Mandela Metropolitan University pending receipt of additional preceptor information. Motion passed 3:1:0:1 with roll call vote as follows:

Barbara Bilek – Yes     Douglas Lang- Yes     Pamela Marshall – No
Anita Parran – Absent   Christina Lindsay – Yes

#A4. Implementation of 2018 Legislation

DISCUSSION: The following discussion was held:

- **SB 826**: Kimberly Grinston stated she met with the Missouri Department of Health and the Missouri Pharmacy Association to discuss implementation of the new ShowMeVax reporting requirements. Ms. Grinston reported some pharmacies may not be able to report by the effective date (8/28/18) due to system compliance requirements and noted ShowMeVax doesn’t currently accommodate all required reportable fields. Board discussion held on possibly delaying enforcement of ShowMeVax reporting; Ron Fitzwater (MPA) indicated significant licensee education may be needed and suggested a six (6) month delay would be minimally appropriate. Board consensus to allow a twelve (12) month enforcement deadline to extend past flu season. Kimberly Grinston asked if both manual or electronic patient notifications would be acceptable; Board consensus to allow both manual and electronic notifications.

- **HB 1719**: Kimberly Grinston asked about including information on the allowed suicide continuing education in the newsletter; Tom Glenski suggested a newsletter article may avoid confusion. Board consensus to include information on suicide training in the upcoming newsletter.

- **Third-Party Logistic Providers (3PL)/Drug Outsourcers**: Kimberly Grinston reported BNDD has advised 3PLs and drug outsourcers may keep their state controlled substance registration even if licensed by the Board under a new category. Kimberly Grinston asked how the Board would like to proceed with 3PL/drug outsourcer licensing; Board consensus to file emergency rules to create and issue a separate 3PL and drug outsourcer license.

#A6. 2019 Legislation

DISCUSSION: The following discussion was held:

- **Pharmacy Technician Proposal**: Board discussion held on the Board’s prior legislative proposal; Suggested changes are included in Attachment A. Board consensus to e-mail proposed changes to Board members and to submit the proposal if no substantive changes are made. Further Board consensus to convene a conference call if substantive questions or changes raised/requested.

Missouri Board of Pharmacy
Open Minutes
July 20, 2018
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338.095: Tom Glenski advised subsection .5 was intended to prevent unlicensed businesses from operating prescription drop-off sites and suggested revising subsection .5 instead of deleting it. Board discussion held; Staff and Board members recommended the following amended language:  

5. It shall be an unauthorized practice of pharmacy and hence unlawful for any person other than a Board licensee or registrant or the patient or the patient’s authorized representative to accept a prescription presented to be dispensed unless that person is located on a premises licensed by the board as a pharmacy.”  

A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve proposed § 338.095 as modified. Motion passed 4:0:0:1 with roll call vote as follows:  

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338.140 (Alternative Agreements): Board discussion held; Board members asked to amend the proposal to clearly provide that a compliance agreement is at the discretion of the Board. Board members expressed support for the following language:  

“Alternatively, at the discretion of the Board, the Board may enter into a voluntary compliance agreement with a licensee, permit holder or registrant to ensure or promote compliance with Chapter 338, RSMO and the rules of the Board in lieu of Board discipline. The agreement shall be a public record. The time limitation identified in section 324.043, for commencing a disciplinary proceeding shall be tolled while an agreement authorized by this section is in effect.”  

A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve proposed § 338.140 as amended. Motion passed 4:0:0:1 with roll call vote as follows:  

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338.160 (Pilot Projects): Pamela Marshall expressed concerns with incorporating an expiration date which could unnecessarily restrict the Board’s options; Christian Tadrus suggested an expiration date may be appropriate given the original goal was to test regulatory programs and gather data. Board discussion held; Suggested changes are included in Attachment B. A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve proposed § 338.160 as amended. Motion passed 3:1:0:1 with roll call vote as follows:  

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Section 338.380 (Well-Being Program): Kimberly Grinston reported the changes are not mandatory but would clarify requirements for the well-being program and possibly attract a compliant bidder. Ms. Grinston stated suggested language was taken from a recently enacted Nursing board statute.  

A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve proposed § 338.380. Motion passed 4:0:0:1 with roll call vote as follows:  

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Anita Parran – Absent     Christina Lindsay – Yes

- Additional Proposals: Douglas Lang reported he recently talked with the Executive Director of the Idaho Board of Pharmacy who indicated fining authority was key to Idaho adopting standards-based regulation. Christian asked if fines would be public; Douglas Lang stated it would depend on the legislation. Board discussion held; Barbara Bilek supported the concept but suggested the Board may not have time to finalize legislative language prior to the deadline for 2019 proposals. Board consensus to consider fining authority during the 2020 legislative discussion.

#A5. 2018 Pharmacist Renewal Process

DISCUSSION: Kimberly Grinston advised the Board’s online renewal system has been modified to allow pharmacists to renew their NOIs at the same time as their pharmacist license, however, the enabling immunization rule will not be effective until 2-3 weeks after renewals are mailed. Ms. Grinston suggested delaying the renewal mailing date until mid-August to allow for joint renewals. Board consensus to delay the pharmacist renewal mailing date to accommodate the recent rule changes and inform licensees of the delay via the Board’s websites/e-alerts.

MOTION TO ADJOURN 5:55 P.M.
At approximately 5:55 p.m., a motion was made by Barbara Bilek, seconded by Christina Lindsay, to adjourn the July 20, 2018 conference call. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – Yes         Douglas Lang- Yes         Pamela Marshall – Yes
Anita Parran – Absent      Christina Lindsay – Yes

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
338.013. Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy technician. Such applicant shall be, at a minimum, legal working age and shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

1. Definitions.
   (1) **Advanced Pharmacy Technician**- A pharmacy technician who is authorized to perform advanced technician functions as defined by the Board by rule.
   
   (2) **Pharmacy Support Staff**- An individual with physical access to a pharmacy, or who has the authority or ability to order legend medication for pharmacy use, but does not assist or support a pharmacist in the practice of pharmacy. Pharmacy Support Staff shall not include individuals with incidental access to the pharmacy while under the direct supervision of a board licensee or registrant, as defined by the Board by rule.
   
   (3) **Pharmacy Technician**- An individual who assists or supports a pharmacist in the practice of pharmacy as defined by Chapter 338, RSMo.
   
   (4) **Pharmacy Technician Trainee**- An individual in training for a pharmacy technician or an advanced pharmacy technician registration.

2. Pharmacy support staff, pharmacy technicians, pharmacy technician trainees and advanced pharmacy technicians must be registered with the board. To be eligible for registration, applicants shall file an application on a form provided by the board with the appropriate fee, complete a criminal background check and comply with the following:
   
   (1) **Pharmacy support staff applicants** must be of legal working age;
   
   (2) **Pharmacy technician trainees** must be at least sixteen (16) years old;
   
   (3) **Pharmacy technician applicants** must be at least sixteen (16) years old and have completed an employer based training program, as provided by the Board by rule. The training program may be tailored to the applicable pharmacy practice as deemed
appropriate by the permitholder or the pharmacist-in-charge. At a minimum, the employer-based training program must include training in the following:

- (a) Pharmacy terminology;
- (b) Pharmacy calculations;
- (c) Dispensing systems;
- (d) Labeling requirements;
- (e) Applicable state and federal pharmacy and drug laws and regulations;
- (f) Record keeping and documentation;
- (g) Proper handling and storage of medications, and;
- (h) Pharmacy policies and procedures.

Advanced Pharmacy Technician applicants must be at least sixteen (16) years old and must have completed an employer based training program as designated by the Board by rule and hold an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies or, for applicants that will be assisting in the practice of nuclear pharmacy, have completed a nuclear pharmacy technician certificate program approved by the Board or from a provider accredited by the Accreditation Council for Pharmacy Education or its successor.

3. Pharmacy Technician Trainees. Registered pharmacy technician trainees may engage in pharmacy technician or advanced pharmacy technician functions for the purpose of training for the applicable registration, as authorized by Board rule and the pharmacist-in-charge.

(1) A pharmacy technician trainee registration may not be renewed or issued to the same applicant more than twice. Individuals who fail to complete training and apply for a pharmacy technician or advanced pharmacy technician registration after the second issuance or renewal period shall be prohibited from reapplying for a trainee registration for a minimum of six (6) months.

(2) In addition to a registered pharmacy technician trainee, a pharmacist-in-charge may designate registered pharmacy support staff or a registered pharmacy technician as a pharmacy technician trainee for the purposes of training. An additional trainee registration is not required. The pharmacy shall maintain a list of all pharmacy support staff and pharmacy technicians.
designated as a pharmacy technician trainee and the training start date. Registered pharmacy support staff and registered pharmacy technicians may not be designated as a pharmacy technician trainee for more than two (2) years. If training is not completed within the required two (2) years, the registrant may not be re-designated as a trainee for a minimum of six (6) months.

24. The board may refuse to issue a certificate of registration as a pharmacy technician registration authorized by this section to an applicant that has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055. Alternately, the board may issue such person a registration, but may authorize the person to work as a pharmacy technician—provided that person adheres to certain terms and conditions imposed by the board. The board shall place on the employment disqualification list the name of an applicant who the board has refused to issue a certificate of registration as a pharmacy technician, or the name of a person who the board has issued a certificate of registration as a pharmacy technician but has authorized to work under certain terms and conditions. The board shall notify the applicant of the applicant's right to file a complaint with the administrative hearing commission as provided by chapter 621.

35. If an applicant has submitted the required fee and an application for registration to the board of pharmacy, the applicant may begin performing activities authorized for the registration class once the completed application has been submitted to the board. The applicant shall keep a copy of the submitted application on the premises where the applicant is employed. If the board refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant shall immediately cease assisting a licensed pharmacist in the practice of pharmacy—performing the applicable technician activities.

46. A certificate of registration issued by the board shall be conspicuously displayed in the pharmacy or place of business where the registrant is employed—available in the pharmacy as provided by the Board by rule.
Every pharmacy technician registrant who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. The registration shall lapse and become null and void thirty days after the expiration date. To renew, an advanced pharmacy technician must submit proof that he/she holds a current and active certification identified in section (3). Proof of certification is not required for individuals renewing a grandfathered advanced pharmacy technician registration issued pursuant to section (13).

The board shall maintain an employment disqualification list. No person whose name appears on the employment disqualification list shall work as a pharmacy technician registrant, except as otherwise authorized by the board. The board may authorize a person whose name appears on the employment disqualification list to work or continue to work as a pharmacy technician registrant provided the person adheres to certain terms and conditions imposed by the board.

The board may place on the employment disqualification list the name of a pharmacy technician registrant who has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055.

After an investigation and a determination has been made to place a person's name on the employment disqualification list, the board shall notify such person in writing mailed to the person's last known address:

1. That an allegation has been made against the person, the substance of the allegation and that an investigation has been conducted which tends to substantiate the allegation;

2. That such person's name has been added in the employment disqualification list of the board;

3. The consequences to the person of being listed and the length of time the person's name will be on the list; and

4. The person's right to file a complaint with the administrative hearing commission as provided in chapter 621.
11. The length of time a person's name shall remain on the disqualification list shall be determined by the board.

12. No hospital or licensed pharmacy shall knowingly employ any person whose name appears on the employee disqualification list, except that a hospital or licensed pharmacy may employ a person whose name appears on the employment disqualification list but the board has authorized to work under certain terms and conditions. Any hospital or licensed pharmacy shall report to the board any final disciplinary action taken against a pharmacy technician registrant or the voluntary resignation of a pharmacy technician registrant against whom any complaints or reports have been made which might have led to final disciplinary action that can be a cause of action for discipline by the board as provided for in subsection 2 of section 338.055. Compliance with the foregoing sentence may be interposed as an affirmative defense by the employer. Any hospital or licensed pharmacy which reports to the board in good faith shall not be liable for civil damages.

13. Grandfather Clause. Any person who holds a current and active pharmacy technician registration on or before January 1, 2020, may apply to the Board for a pharmacy support staff, pharmacy technician or advanced pharmacy technician registration without fee, provided the application must be submitted by May 31, 2020. To be eligible for a grandfathered advanced pharmacy technician registration under this subsection, the application must be accompanied by a statement from a Missouri licensed pharmacist attesting that the applicant has practiced as a pharmacy technician for a minimum of 2,080 hours and that such practice included, in whole or in part, the performance of advanced technician duties as designated by the Board by rule. If a grandfathered registration issued pursuant to this subsection is allowed to lapse, the former registrant shall be treated in the same manner as a new applicant and must comply with all applicable training and registration requirements upon reapplication.
338.160. The Board of Pharmacy may approve, modify and establish requirements for pharmacy pilot or demonstration research projects designed to enhance patient care or safety, improve patient outcomes or expand access to pharmacy services. To be approved, pilot or research projects shall be within the scope of the practice of pharmacy as defined by Chapter 338, RSMo, be under the supervision of a Missouri licensed pharmacist and comply with applicable compliance and reporting requirements as established by the Board by rule, including, any staff training or education requirements. Board approval shall be limited to a period of up to eighteen (18) months, provided the Board may grant an additional six (6) months extension if deemed necessary or appropriate to gather or complete research data or if deemed in the best interests of the patient. The Board may rescind approval of a pilot project at any time if deemed necessary or appropriate in the interest of patient safety. The provisions of this subsection shall expire on August 28, 2023. The Board shall provide a final report on approved projects and related data or findings to the Missouri General Assembly on or before December 31, 2022. The name, location, approval dates, general description of and responsible pharmacist for an approved pilot or research project shall be deemed an open record.
#4 FDA Compounding Memorandum of Understanding Response

- Draft Response (12-18)
#5 Rx Cares for Missouri Updates

- Draft Contract
- Draft Emergency Rule
Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 9—Rx Cares for Missouri Program

EMERGENCY RULE

20 CSR 2220-9.010 Rx Cares For Missouri Program

PURPOSE: This rule establishes the Missouri Board of Pharmacy’s medication disposal program as part of the Rx Cares for Missouri program created by section 338.710, RSMo and establishes standards/criteria for Program operation and participation.

(1) Section 338.710 established the “Rx Cares for Missouri Program” within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse and diversion in Missouri. As part of the Rx Cares for Missouri Program, the Board is hereby establishing a medication destruction and disposal program (the “Program”) for the purposes of collecting unused or unwanted medication from the public for disposal in accordance with state and federal law. Operation of the Program may be delegated to a Board approved vendor or third-party.

(2) Eligible Participants. To be eligible for participation, applicants must be physically located in Missouri and currently registered to collect unwanted controlled substances with the United States Drug Enforcement Administration (“DEA”) and the Missouri Bureau of Narcotics and Dangerous Drugs (“BNDD”) unless exempt from registration by state or federal law. Additionally, the applicant must be:

(A) A licensed Missouri pharmacy or drug distributor;
(B) A licensed healthcare provider authorized to prescribe controlled substances;
(C) A hospital, office, clinic or other medical institution that provides health care services;
(D) A federal, state, local or municipal public health, law enforcement or other governmental agency, or
(E) A higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the United States Secretary of Education.

(3) Participant Requirements. Approved participants must establish and operate a public medication collection program in compliance with Program requirements, including, but not limited to, all applicable Board or vendor requirements for collecting, submitting, or forwarding
medication for destruction and disposal. Participants must promptly enroll in the Program after notification of approval is received from the Board.

(A) Subject to appropriation, approved Program participants will be provided a collection receptacle and inner liners to be used for collecting medication pursuant to the Program. Participants may alternatively use an existing collection receptacle if approved by the Board or the Program vendor. Program Participants are responsible for installation of the collection receptacle in accordance with vendor requirements.

(B) Collection receptacles must be physically located in the state of Missouri at an address approved by the Board. A Board approved sign must be located on or near the receptacle indicating that the collection program has been funded by the Missouri Board of Pharmacy as part of the Rx Cares for Missouri Program. Collection receptacles may not be used to dispose of medication from the pharmacy’s inventory.

(C) Medication must be collected and handled in compliance with all state and federal controlled substance laws. Once collected, medication may be submitted to the vendor or the vendor’s authorized designee for disposal up to a maximum of twenty-four (24) times per collection receptacle. Program Participants may arrange for additional medication disposal at the Participant’s cost.

(D) Program Participants must notify the Board in writing within ten (10) days after terminating Program participation. Unless otherwise agreed by the Board for good cause, Program Participants shall reimburse the Board for the cost of the collection receptacle if the Participant terminates participation prior to Program completion. Collection receptacle costs must be remitted to the Board within sixty (60) days after Board notification.

(4) Application Procedures. Applications to participate in the Program must be submitted to the Board on a Board approved form and include-

(A) The applicant’s name, address, contact telephone number and e-mail address;

(B) The Missouri address where the collection receptacle will be located;

(C) A copy of the applicant’s DEA and BNDD controlled substance registrations;

(D) A description of how the medication collection program will be operated, including, operational times and how the program will be advertised to the public;

(E) A designation of whether the applicant will be using a Board approved collection receptacle or supplying their own collection receptacle subject to vendor approval; and

(F) A description of the need for a medication collection program in the proposed collection site area along with any supporting data or evidence.

(5) Approval Criteria. At the discretion of the Board, a maximum of one-hundred (100) applicants will be approved for Program participation subject to funding availability. The following criteria will be considered by the Board when reviewing applications-

(A) The need for a medication collection program in the proposed collection site area, including, but not limited to, any alternative collection programs/opportunities available;
(B) Relevant evidence or data regarding drug use, abuse, fatalities or trends;
(C) The number of applications submitted or previously approved by the Board for the applicant regardless of collection site;
(D) The nature and structure of the proposed collection program, including, but not limited to, operational times and any public restrictions;
(E) Available staff, resources or expertise;
(F) Any state, federal or local disciplinary action, including, any pending Board complaints or investigations;
(G) The applicant’s compliance with state and federal drug and controlled substance laws;
(H) The applicant’s financial need and available resources; and
(I) Any other factor that may be relevant to the applicant’s ability to participate in or comply with the Program.

(6) Information Sharing. As a condition of participation, applicants must agree that Program information collected or maintained by the vendor or the vendor’s designee may be disclosed to:
(A) The Board or the Board’s authorized designee on request; and
(B) The Missouri Governor and the Missouri General Assembly pursuant to § 338.710, RSMo.
Proposed 2019 Legislation

- ED Memo
- Pilot Projects
- Pharmacy Technician Proposal
- Pharmacy Practice Advancement
TO:       Board Members

FROM:    Kimberly Grinston,
              Executive Director

RE:       2019 Proposed Legislation

DATE:   December 3, 2018

The Governor's Office approved the following Board legislative proposals for 2019:

1. Alternative compliance agreements in lieu of discipline
2. Allowing licensees to accept prescriptions outside of a licensed pharmacy, &
3. Board approved pilot projects.

The Governor's Office did not approve the pharmacy technician proposal (additional information will be provided on the conference call). The Board was asked to streamline legislative proposals and I indicated the well-being clean-up language was not as pressing as the Board's other proposals. Accordingly, the Department did not submit the well-being proposal for official review.

Senator Sater will likely sponsor the Board’s bills and has expressed concerns the pilot project proposal would grant the Board unlimited authority to waive Chapter 338 requirements. Senator Sater is interested in the concept but asked the Board to narrow the proposal to specific types of pilot projects.

For example, the Board previously discussed pilot projects that would:

1) Enhance the use of technology in providing pharmacy services, or
2) Allow expanded technician duties under the supervision of a pharmacist (tech-check-tech or technology-check-tech).

While these concepts could be addressed by rule, the Board discussed having statutory authority to approve these concepts in a limited setting before adopting a comprehensive approach.

How would the Board like to proceed?
338.160. The Board of Pharmacy may approve, modify and establish requirements for pharmacy pilot or demonstration research projects designed to enhance patient care or safety, improve patient outcomes or expand access to pharmacy services. To be approved, pilot or research projects shall be within the scope of the practice of pharmacy as defined by Chapter 338, RSMo, be under the supervision of a Missouri licensed pharmacist and comply with applicable compliance and reporting requirements as established by the Board by rule, including, any staff training or education requirements. Board approval shall be limited to a period of up to eighteen (18) months, provided the Board may grant an additional six (6) months extension if deemed necessary or appropriate to gather or complete research data or if deemed in the best interests of the patient. The Board may rescind approval of a pilot project at any time if deemed necessary or appropriate in the interest of patient safety. The provisions of this subsection shall expire on August 28, 2023. The Board shall provide a final report on approved projects and related data or findings to the Missouri General Assembly on or before December 31, 2022. The name, location, approval dates, general description of and responsible pharmacist for an approved pilot or research project shall be deemed an open record.
#8 Special Sites/Non-Pharmacists Applications

- Conduent
- Lafayette Regional Health Center
- North Colorado Family Medicine Clinic
- PillarRx Consulting
- St. Louis VA- North County
- St. Louis VA- St. Charles County