Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 3:00 p.m. on March 13, 2019 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 MO Blvd., Jefferson City, Missouri at 3:00 p.m. on March 13, 2019. They may also call 573-526-5808 (local) or 866-630-9351 (toll-free)

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.
MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

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

March 13, 2019
3:00 p.m.

OPEN SESSION AGENDA

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

2. Roll Call

3. Approval of Minutes
   a. January 9-10, 2019

4. 2019 Legislative Update

5. Chapter 338 Review
   a. 338.056
   b. 338.085

6. Pharmacy Technician Authorized Duties/Community Health Workers
   a. Executive Director Memorandum
   b. MPA DSME Program
   c. MPA February 2019 Article

7. Class-O Automated Dispensing Systems Survey
   a. Executive Director Memorandum

8. Required Inspections for Non-Resident Pharmacy, Drug Distributor, 3PL and Outsourcer Change of Ownership Applications
   a. Executive Director Memorandum
   b. 20 CSR 2220-2.025
   c. 20 CSR 2220-8.030

9. Rx Cares for Missouri Patient Counseling Educational Campaign

10. Approval of Special Sites/Non-Pharmacist Preceptors (*= new applicant)
   a. Battle Creek Veterans Affairs Medical Center*
b. Veterans Affairs of St. Louis Health Care System- Washington Community Based Outpatient Clinic*

c. CVS Pharmacy Business Management*

d. EPI-Q, Inc.*

e. Haskell Indian Health Center*

f. Maternal Fetal Care Center at SSM Health St. Mary’s*

11. Executive Director Office Updates

12. Future Meeting Dates/Times

13. The Board may go into closed session at any point during the meeting and all 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.

14. Adjournment
3. **Approval of Minutes**
   a. January 9-10, 2019
The Missouri Board of Pharmacy met in open session 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 R. Lang, R.Ph., Vice-President
James Gray, PharmD., Member
Colby Grove, 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
Jennifer Boehm, Administrative Coordinator
Sarah Decker, Compliance Coordinator
Andi Miller, PharmD, Inspector
Scott Spencer, R.Ph., Inspector
Lisa Thompson, R.Ph., Inspector
Dan Vandersand, R.Ph., Inspector
Elaina Wolzak, R.Ph., Inspector
Barbara Wood, R.Ph., Inspector

**Others Present**
Curtis Thompson, Legal Counsel

President Christian Tadrus called the meeting to order at approximately 8:06 a.m. on January 9, 2019, and welcomed new Board members James Gray and Colby Grove.

**MOTION FOR CLOSED SESSION (8:09 A.M.)**
A motion was made by Pamela Marshall, seconded by Christina Lindsay, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section
610.021(1), (3), (5), (6), (7), (13) and (14), RSMo. Motion passed 6:0:0:0 by roll call vote as follows:

   Colby Grove – Yes   James Gray- 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 reconvened in open session at approximately 8:37 a.m. on January 10, 2019 and roll call was taken. President Christian Tadrus welcomed new Board members James Gray and Colby Grove.

#B3- Agenda Additions/ Corrections

DISCUSSION: Kimberly Grinston reported #B23A (Distinguished Pharmacy) has been added to the open agenda.

#B4- Approval of Open Session Minutes.

- October 24-25, 2018 Minutes
- November 14, 2018 Minutes
- December 12, 2018 Minutes
- August 14-15, 2018 Minutes
- September 5, 2018 Minutes
- September 19, 2018 Minutes
- October 24-25, 2018 Minutes

DISCUSSION:

- November 14, 2018, Minutes- A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the November 14, 2018 minutes. Motion passed 4:0:2:0 by roll call vote as follows:

      Colby Grove – Abstain   James Gray- Abstain       Douglas Lang- Yes
      Pamela Marshall – Yes   Anita Parran – Yes       Christina Lindsay- Yes

- December 12, 2018, Minutes- A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the December 12, 2018 minutes. Motion passed 4:0:2:0 by roll call vote as follows:

      Colby Grove – Abstain   James Gray- Abstain       Douglas Lang- Yes
      Pamela Marshall – Yes   Anita Parran – Yes       Christina Lindsay- Yes

- August 14-15, 2018, Minutes- A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the August 14, 2018, minutes. Motion passed 4:0:3:0 by roll call vote as follows:
Colby Grove – Abstain  James Gray- Abstain  Douglas Lang- Yes
Pamela Marshall – Yes  Anita Parran – Yes  Christina Lindsay- Abstain

- **September 5, 2018, Minutes:** A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the September 5, 2018 minutes. Motion passed 4:0:2:0 by roll call vote as follows:
  Colby Grove – Abstain  James Gray- Abstain  Douglas Lang- Yes
  Pamela Marshall – Yes  Anita Parran – Yes  Christina Lindsay- Yes

- **September 19, 2018, Minutes:** A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the December, 2018 minutes. Motion passed 4:0:2:0 by roll call vote as follows:
  Colby Grove – Abstain  James Gray- Abstain  Douglas Lang- Yes
  Pamela Marshall – Yes  Anita Parran – Yes  Christina Lindsay- Yes

- **October 24-25, 2018 Minutes:** A motion was made by Christina Lindsay, seconded by Anita Parran, to approve the October 24-25, 2018, minutes. Motion passed 3:0:3:0 by roll call vote as follows:
  Colby Grove – Abstain  James Gray- Abstain  Douglas Lang- Abstain
  Pamela Marshall – Yes  Anita Parran – Yes  Christina Lindsay- Yes

#B6 Board Member/Meetings Report

**DISCUSSION:** The following Board reports were received:

- Pamela Marshall attended the NABP Board Member meeting in November 2018 which focused on medication safety. Discussion topics included non-traditional dispensing models, the role of the PIC, mutual license recognition and the opioid crisis. Christian Tadrus asked about the PIC discussion; Pamela Marshall noted states like Maryland and Wyoming focus on the permit holder when imposing discipline.

- Pamela Marshall reported she met with the Missouri schools of pharmacy to discuss patient counseling and ways to promote better counseling/patient engagement. A follow-up conference call was held on December 18, 2018, several proposals are under discussion, including, interactive webinars with case studies.

- Douglas Lang attended the annual American Society of Pharmacy Law meeting in South Carolina. The program was well-attended and focused on emerging pharmacy issues. The 2019 conference will be held in San Diego.

#B8 Rx Cares for Missouri Implementation

**DISCUSSION:** Kimberly Grinston advised the 2019 public relations campaign was relaunched in January; a date for the Center for Patient Safety training is still pending. Ms. Grinston advised the Office of Administration mistakenly posted the Rx Cares for Missouri contract on January 7th; Ms. Grinson stated the Board previously reviewed...
contract language and no major changes were made. Board consensus to hold rule approval until after bid proposals are received.

#B10 Nuclear Pharmacy Rule Revision
- Douglas Lang reported the Working Group finalized their suggestions, however, Board staff provided additional comments. The Working Group will be meeting on January 16th to discuss proposed staff changes with the Working Group; Final revisions will be presented to the Board at the February meeting. Public attendees will be provided call-in numbers to participate in the February conference call.
- Douglas Lang reported Board members toured Mid-America Isotopes; Board members stated the visit was educational and provided insight into nuclear pharmacy.

#B12 Standardization of Board Procedures

DISCUSSION: Board members expressed support for the standard review procedures and suggested:
- Adding a discussion start date for pending items
- Adding a statute/rule category to identify the regulatory approach
- Providing information before a board meeting on which review stage an item is in
- Identifying items on the Board’s strategic plan
- Adding legislative proposals
- Adding inspector suggested review topics
- Listing current or potential stakeholders

Further Board consensus to send an electronic survey for ranking pending items.

#B16 Applications for Intern Training Special Site/Non-Pharmacist Preceptors

- Mercy Clinic Family Medicine
- National Community Pharmacy Association
- Prescribe Right
- San Jacinto College
- Jordan Valley Community Health Center
- Pharmacy First

DISCUSSION: Tom Glenski recommended approval of the special site/non-pharmacist preceptors listed. Douglas Lang asked staff to identify which sites/preceptors are new vs. renewals. A motion was made by Christina Lindsay, seconded by Douglas Lang, to approve the special sites and non-pharmacist preceptors listed. Motion passed 6:0:0:0 by roll call vote as follows:

<table>
<thead>
<tr>
<th>Name</th>
<th>Vote</th>
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<tbody>
<tr>
<td>Colby Grove</td>
<td>Yes</td>
</tr>
<tr>
<td>Pamela Marshall</td>
<td>Yes</td>
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<tr>
<td>James Gray</td>
<td>Yes</td>
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<td>Anita Parran</td>
<td>Yes</td>
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<tr>
<td>Douglas Lang</td>
<td>Yes</td>
</tr>
<tr>
<td>Christina Lindsay</td>
<td>Yes</td>
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</tbody>
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Missouri Board of Pharmacy
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Pamela Marshall reported the states discussed during the recent NABP meeting allowing the schools of pharmacy to approve intern sites/preceptors based on ACPE standards. Douglas Lang asked if the Board could delegate approval of renewed sites/preceptors if no changes have been made. Board consensus to discuss delegating renewal of approved sites during strategic planning.

#B17 Intern/Special Site Regulation

**DISCUSSION:** Kimberly Grinston reported the Board previously asked to amend the rules to only allow interns to renew twice after graduation from pharmacy school. Board discussion held on the validity of the NAPLEX score; Kimberly Grinston advised the Board previously voted to maintain the current NAPLEX score requirements. Board discussion held on limiting the allowed number of hours for special sites and requirements for special sites to ensure appropriate pharmacy-related training. Douglas Lang asked if the special site language needs to be broadened to address alternative sites; James Gray expressed support for maintaining broad authority given changes in healthcare delivery models. Christian Tadrus asked of there were concerns with the number of hours that can be earned at a special site; James Gray suggested ACPE requirements may address the concerns. Christina Lindsay stated ACPE guidelines limit the number of elective training courses a student can take which may alleviate the need for Board action. Anita Parran suggested the school’s vetting should be sufficient. Board consensus no additional changes are needed on special site requirements; Further consensus to discuss the need to approve special sites during strategic planning.

#B9 Temperature Control/Cold-Chain Management for Prescription/Medication Delivery

**DISCUSSION:** Christian Tadrus opened the listening session; Public attendees were advised comments may need to be limited to accommodate all participants. The following comments were received:

- Loretta Boessing stated her son is a liver transplant patient who received medication in June 2017 that was delivered during record-breaking heat. Ms. Boessing indicated the medication was physically hot when received and that her son subsequently experienced elevated lab results that she believes were related to the warm medication. Ms. Boessing alleged she was told medication is routinely delivered to Missouri patients in bubble mailers without appropriate temperature control packaging/mechanisms. Ms. Boessing stated her goal is to guarantee the safety of all patients and to ensure patients are not forced to use mail-order pharmacies. Ms. Boessing urged the Board to enact regulation to: (1) prohibit mandatory mail-order requirements, (2) require temperature monitoring in delivery vehicles/warehouses, (3) transparency of testing data, (4) tracking of temperature data for all medication and not just refrigerated medications via monitors or other equipment and (5) address medication being exposed to temperatures for extended periods of time by being left outside or in a mailbox.
Ms. Boessing asked the Board to take action to ensure medications are not shipped outside of the temperature range proven to be safe.

- Ron Fitzwater suggested requiring that patients have an opportunity to opt-in to mail-order delivery and addressing PBM regulation on the business side. Mr. Fitzwater noted patients have no place to address PBM business operations and reported MPA would continue to advocate on both of these issues.

Board discussion held; Pamela Marshall noted this is a patient safety concern and suggested additional research may be needed especially given documented climate changes. Douglas Lang suggested having Inspectors review temperature procedures/controls during inspection. James Gray suggested there doesn’t appear to be a clear best practice standard and suggested additional research/data collection may be appropriate. Mr. Gray noted federal changes may be needed to fully address the concerns raised. Board consensus to: (1) gather inspectional data, (2) research what temperature control options/products are available today, (3) clarify the Board’s legal authority over the supply chain, (4) research data on effects of extreme temperatures, (5) ask the Department of Insurance for comments and (6) contact USP and FDA for expertise or data.

#B10 Veterinary Compounding for Office Use
- Discussion rule Draft- 20 CSR 2220-2.400
- Missouri Veterinary Association Correspondence
- FDA Correspondence

DISCUSSION: Kimberly Grinston advised she met with the Missouri Veterinarian Board regarding the proposed language from the Missouri Veterinarian Association (MVA) and the Board’s concerns regarding Board authority to impose supply limits for veterinarians. Ms. Grinston advised the Missouri Veterinarian Board supported MVA’s language and would consider their Board’s authority/willingness to incorporate supply limits. Douglas Nelson and Dr. Cliff Miller reiterated the need for the proposed change; Dr. Miller further indicated federal law would prohibit mass compounding for office use for food animals. Board discussion held; Board members supported the proposed rule draft but asked to hold approval until after the Veterinarian Board’s January meeting where the matter will be discussed.

#B23A DISTINGUISHED PHARMACY

ITEMS ENCLOSED:
- Notice of Disciplinary Hearing
- Hager Letter
- Complaint
- Notice of Proof of Service
- Default Decision
DISCUSSION: The Board convened a disciplinary hearing at approximately 11:53 a.m. Alicia Embly-Turner was present as counsel for the Board. Distinguished Pharmacy was not present and was not represented by counsel. Ms. Turner provided an opening statement and presented exhibits 1-5. A closing statement was provided. The hearing adjourned at approximately 11:57 a.m. A hearing transcript is available at the Board’s office.

#B7. 2019 Proposed Legislation
- Pre-filed Legislative Bills
- Board Approved Pilot Projects
- Pharmacy Technician Proposal

DISCUSSION: Phillip Arnzen, Division of Professional Registration- Legislative Liaison, was introduced to the Board. The following Board discussion held:

- Douglas Lang suggested SB 155 (PDMP) address the required timeframe for submitting reports between the passage and implementation of the legislation; Mr. Lang further suggested the proposal address/require mandating zero reporting. Pamela Marshall suggested the bill include C-V reporting. Christian Tadrus asked if there were fiscal note concerns; Douglas Lang noted a significant number of pharmacies may already be reporting to the St. Louis County PDMP program.
- Pamela Marshall and Christina Lindsay suggested HB 251 recommend suicide training for all pharmacists vs. retail pharmacists only.
- Douglas Lang noted HB 195 (mandatory e-prescribing) would include both controlled and non-controlled substances; Christian Tadrus suggested all pharmacies may not have electronic capability.
- Pilot Projects: Kimberly Grinston advised the agenda includes revised pilot project language as requested by Senator Sater; Phillip Arnzen stated Senator Sater’s office asked for a narrower description of the type of programs the Board wants to approve. Board discussion held; A motion was made by Douglas Lang, seconded by Anita Parran, to approve the pilot project language presented. Motion passed 6:0:0:0 by roll call vote as follows:
  Colby Grove – Yes    James Gray- Yes    Douglas Lang- Yes
  Pamela Marshall – Yes Anita Parran – Yes    Christina Lindsay- Yes

Phillip Arnzen will consult with Senator Sater’s office and advise if additional language is needed.

THE BOARD RECESSED FOR LUNCH AT 12:29 P.M. The Board reconvened at 1:35 P.M.

#B13 Class-O Automated Dispensing Systems

DISCUSSION: The following comments were revised:
• Allison Smith asked how the Class-O permit would apply to Class-B pharmacies using an automated machine to dispense to a nurse pursuant to a patient-specific prescription. Ms. Smith expressed concerns regarding improper regulation of traditional hospital/medical clinic dispensing. Tom Glenski advised the rule would only apply to patient-specific prescriptions by the pharmacy.

• Ron Fitzwater expressed concerns about the impact on retail pharmacies and ensuring a level playing-field. Mr. Fitzwater noted some states have included mandatory distance requirements for automated machines from a traditional brick and mortar pharmacy. Mr. Fitzwater noted the rule appears to conflict with MPA’s message that pharmacist involvement and face-to-face interactions are important and should be encouraged not eliminated.

• Samuel Leveritt noted section (3)(B) only requires notification to patients that counseling will be provided if requested which is different from other practice settings.

• John Sisto from Express Scripts suggested the Board be mindful that use and implementation of technology is what’s important and suggested review of the types and communication the Board prefers. Mr. Sisto suggested the Board focus on the desired outcome as opposed to the type of technology.

• Caleb Witt (Pharmax Pharmacy) noted most urgent care clinics have dispensing machines that are not under pharmacist supervision. Mr. Witt expressed support for enhancing patient access and opportunities for care.

Christian Tadrus asked if concerns exist with lowering or establishing different standards of practice; Mr. Lang suggested the rule would allow pharmacists to leverage technology to meet the patient’s needs and not alter practice standards. Tom Glenski suggested the Board may have legal issues with both 20 CSR 2220-2.900 and 20 CSR 2220-2.925 being effective at the same time. Mr. Glenski recommended amending 20 CSR 2220-2.900 also. James Gray recommended revising 20 CSR 2220-2.900 and 20 CSR 2220-2.925 at the same time. Board discussion held; Board consensus to revise 20 CSR 2220-2.900 and 20 CSR 2220-2.925 jointly. The following issues were identified for further identification in 20 CSR 2220-2.925: supervision, location, drug storage, machine ownership, distance requirements and underserved areas.

A motion was made by Douglas Lang to approve the proposed rule language for filing and public comment. Motion died for a lack of a second. Pamela Marshall asked for additional information on small business impact. Board consensus to review at the April meeting for definition of Board requested standards along with information on small business impact.

#B7. 2019 Proposed Legislation (Cont’d)
• Pre-filed Legislative Bills
• Board Approved Pilot Projects
• Pharmacy Technician Proposal
DISCUSSION: Phillip Arnzen advised he consulted with Senator Sater’s office who is still requesting additional definition on the types of pilot projects the Board would like to approve; Board discussion held. Pamela Marshall requested to consult with legal counsel.

Christian Tadrus asked to review pharmacy technician legislation; Kimberly Grinston advised MHA has been working on proposed language. Ron Fitzwater advised draft language has been circulated, however, additional recommendations were made by the MPA’s legal counsel. Mr. Fitzwater advised MPA will be discussing the language with MHA and MSHP; a bill is anticipated this legislative session. Phillip Arnzen indicated the Governor’s Office is concerned that broad certification would be too burdensome for technicians and not in line with the Governor’s current goal of increasing access to job opportunities. Mr. Arnzen suggested the Board may want to focus on specialty areas where a strong patient safety justification exists. Board consensus to discuss with legal counsel prior to suggesting language.

#B14 2020 Legislation/Chapter 338 Review

- General Discussion on Proposed Chapter 338 Review Process/Focus Areas

DISCUSSION: Kimberly Grinston presented the proposed schedule and requested direction on how the Board would like to proceed with the review; Board consensus to focus on Group # 1- Pharmacist Scope of Practice. Ron Fitzwater reported two proposals have been filed by Senator Sater on behalf of MPA related to pharmacist prescribing/scope of practice and dispensing of smoking cessation medication. Mr. Fitzwater noted the prescribing/scope of practice language was drafted by the Pharmacist Advancement Coalition. Caleb Witt spoke in favor of allowing pharmacist adaptation services to maximize and enhance patient care. Board consensus to review pharmacist adaptation as part of the Chapter 338 review.

#B15 REMOTE DATA ENTRY

- Discussion Draft

DISCUSSION: Christina Lindsay questioned if the remote data entry site would have to be licensed as a pharmacy; Kimberly Grinston advised a pharmacy permit would not need a license but the supervising pharmacy would. Tom Glenski suggested limiting the rule to just electronic records; Board consensus to limit as suggested. Mr. Lang further suggested no print or storage capability should be allowed at the remote data entry sites; Christian Tadrus noted prohibiting print capabilities would significantly limit allowed systems.

- Ryan Butler (Genoa Healthcare) asked if the proposal would redefine direct supervision; Kimberly Grinston advised the Board would be defining acceptable supervision.
- Christian Tadrus asked if the Board would require access at a specific location or allow portable laptops; Douglas Lang suggested restricting
activities to a specific address/residence. Mr. Lang stressed confidentiality must be maintained at the location.

- Christian Tadrus asked if the Board should require a designated room similar to Class-I; Mr. Tadrus suggested the Board consider authorized technician activities outside of a pharmacy. James Gray asked if remote data entry would be an advanced technician function.
- Pamela Marshall expressed concerns with ensuring HIPAA compliance.
- Christian Tadrus suggested the supervising pharmacy should be located in the state of Missouri.
- Tom Glenski noted the rule intended to address data entry and not data collection or patient contact; Douglas Lang suggested the rule specifically and clearly allow data entry only.
- Douglas Lang suggested the rule allow audio or electronic communication with the pharmacy/pharmacist.
- Samuel Leveritt suggested allowing intranet location with security standards to prevent unauthorized contact/review.
- Christina Lindsay—add 3rd party rejections and prior authorization.

Board consensus to review at a future meeting.

#B18 Inspection/Investigation Report

DISCUSSION: Tom Glenski indicated his report was in the Board’s handouts; No Board discussion held.

#B5 General Administration Report

DISCUSSION: Kimberly Grinston reported a joint webinar with BOHA will be rescheduled for February; Ms. Grinston asked Board members to contact her if they are interested in attending NABP’s annual meeting.

#B20 Hospital Advisory Committee Update

DISCUSSION: David Wolfrath advised the last meeting was in October 2018; the next meeting is scheduled on January 16th as a conference call. HAC members are working on committee appointments. The DHSS pharmacy rule is still pending; Updates will be provided once known.

MOTION FOR CLOSED SESSION (4:01 P.M.)

At 4:01 p.m., A motion was made by Christina Lindsay, seconded by Douglas Lang, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (6), (7), (13) and (14), RSMo. Motion passed 6:0:0:0 by roll call vote as follows:

RETURN TO OPEN

By motion duly made and recorded in the closed session minutes, the Board returned to open session at 4:45 p.m.

#B7.  2019 Proposed Legislation (Cont’d)
   • Pre-filed Legislative Bills
   • Board Approved Pilot Projects
   • Pharmacy Technician Proposal

DISCUSSION: A motion was made by Douglas Lang, seconded by James Gray, to request authority to approve pilot projects related to technology assisted verification and remote medication dispensing. Motion passed 6:0:0:0 by roll call vote as follows:

Board consensus to grant staff authority to support the proposed pilot projects jointly or singularly. Further Board consensus to monitor MPA’s anticipated legislative proposals prior to further action on the pharmacy technician proposal.

MOTION TO ADJOURN (4:49 P.M.)
A motion was made by Douglas Lang, seconded by Christina Lindsay, to adjourn the January 2019 meeting. Motion passed 6:0:0:0 by roll call vote as follows:

The meeting was adjourned.

_________________________________
KIMBERLY GRINSTON
EXECUTIVE DIRECTOR
4. **2019 Legislative Update**
5. Chapter 338 Review
   a. 338.056
   c. 338.085
TO: Board Members

FROM: Kimberly Grinston, 
   Executive Director

RE: Chapter 338 Review

DATE: March 7, 2019

Pursuant to the Board’s Chapter 338 legislative review, the following statutes are included in the agenda for review on the conference call:

- Section 338.056 (Generic substitutions)
- Section 338.085 (Interchangeable biological products)

The Board will not be developing specific language on the call. Instead, we’re asking Board members to generally define/identify suggested changes or concepts along with any research requests. Staff will draft specific language for Board review at the April meeting based on the comments received. Comments/suggestions can also be e-mailed to me prior to the meeting.

The following statutes are scheduled for initial review/discussion in April:

- Section 338.200 (Pharmacist dispensing of emergency prescriptions)
- Section 338.210 (Pharmacy defined)
- Section 338.202 (Maintenance medications)
- Section 338.400 (Blood clotting therapies)
338.056. Generic substitutions may be made, when, requirements —

violations, penalty. — 1. Except as provided in subsection 2 of this section, the
pharmacist filling prescription orders for drug products prescribed by trade or brand
name may select another drug product with the same active chemical ingredients of the
same strength, quantity and dosage form, and of the same generic drug or
interchangeable biological product type, as determined by the United States Adopted
Names and accepted by the Federal Food and Drug Administration. Selection pursuant
to this section is within the discretion of the pharmacist, except as provided in
subsection 2 of this section. The pharmacist who selects the drug or interchangeable
biological product to be dispensed pursuant to this section shall assume the same
responsibility for selecting the dispensed drug or biological product as would be incurred
in filling a prescription for a drug or interchangeable biological product prescribed by
generic or interchangeable biologic name. The pharmacist shall not select a drug or
interchangeable biological product pursuant to this section unless the product selected
costs the patient less than the prescribed product.

2. A pharmacist who receives a prescription for a brand name drug or biological
product may select a less expensive generically equivalent or interchangeable biological
product unless:

   (1) The patient requests a brand name drug or biological product; or
   (2) The prescribing practitioner indicates that substitution is prohibited or displays
       “brand medically necessary”, “dispense as written”, “do not substitute”, “DAW”, or words
       of similar import on the prescription.

3. No prescription shall be valid without the signature of the prescriber.

4. If an oral prescription is involved, the practitioner or the practitioner's agent,
   communicating the instructions to the pharmacist, shall instruct the pharmacist as to
   whether or not a therapeutically equivalent generic drug or interchangeable biological
   product may be substituted. The pharmacist shall note the instructions on the file copy
   of the prescription.

5. Notwithstanding the provisions of subsection 2 of this section to the contrary, a
   pharmacist may fill a prescription for a brand name drug by substituting a generically
equivalent drug or interchangeable biological product when substitution is allowed in accordance with the laws of the state where the prescribing practitioner is located.

6. Violations of this section are infractions.

338.085. Interchangeable biological products, pharmacist may dispense as substitute, when — recordkeeping — rulemaking authority. — 1. As used in this chapter, the following terms shall mean:

(1) "Biological product", the same meaning as such term is defined under 42 U.S.C. Section 262;

(2) "Interchangeable biological product", a biological product that the Food and Drug Administration:

(a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. Section 262(k)(4); or

(b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

2. A pharmacist may substitute an interchangeable biological product for a prescribed product only if all of the following conditions are met:

(1) The substituted product has been determined by the Food and Drug Administration to be an interchangeable biological product with the prescribed biological product;

(2) The substitution occurs according to the provisions of section 338.056; and

(3) The pharmacy informs the patient of the substitution.

3. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist’s designee shall make an entry of the specific product provided to the patient including the name of the product and manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one of the following means:

(1) An interoperable electronic medical records system;

(2) An electronic prescribing technology;

(3) A pharmacy benefit management system; or

(4) A pharmacy record.

4. Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, if an entry cannot be made
under the provisions of subsection 3 of this section, the pharmacist shall communicate
the biological product dispensed to the prescriber using facsimile, telephone, electronic
transmission, or other prevailing means, except that communication shall not be
required if:

   (1) There is no Food and Drug Administration approved interchangeable biological
product for the product prescribed; or

   (2) A refill prescription is not changed from the product dispensed on the prior filling
of the prescription.

  5. The pharmacist shall maintain records in a manner consistent with section
  338.100.

  6. The pharmacist shall label prescriptions in a manner consistent with section
  338.059.

  7. The board of pharmacy shall maintain a link on its website to the current list of all
biological products determined by the Food and Drug Administration to be
interchangeable with a specific biological product.

  8. The board of pharmacy may promulgate rules for compliance with the provisions
of this section. Any rule or portion of a rule, as that term is defined in section 536.010,
that is created under the authority delegated in this section shall become effective only if
it complies with and is subject to all of the provisions of chapter 536 and, if applicable,
section 536.028. This section and chapter 536 are nonseverable and if any of the
powers vested with the general assembly pursuant to chapter 536 to review, to delay
the effective date, or to disapprove and annul a rule are subsequently held
unconstitutional, then the grant of rulemaking authority and any rule proposed or
adopted after August 28, 2016, shall be invalid and void.

(L. 2016 S.B. 875)
6. Pharmacy Technician Authorized Duties/Community Health Workers
   d. Executive Director Memorandum
   e. MPA DSME Program
   f. MPA February 2019 Article
7. Class-O Automated Dispensing Systems Survey
   b. Executive Director Memorandum
8. **Required Inspections for Non-Resident Pharmacy, Drug Distributor, 3PL and Outsourcer Change of Ownership Applications**
   d. Executive Director Memorandum
   e. 20 CSR 2220-2.025
   f. 20 CSR 2220-8.030
 PURPOSE: This rule establishes licensure guidelines for nonresident pharmacies.

(1) Nonresident pharmacies shall not ship, mail, or deliver prescription drugs into Missouri without first obtaining a pharmacy license from the Missouri Board of Pharmacy. An exemption to licensure is allowed when a nonresident pharmacy provides a prescription drug in an emergency situation or supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located.

(2) To obtain a Missouri pharmacy license, a nonresident pharmacy must—

(A) Maintain a pharmacy license in good standing from the state in which the nonresident pharmacy is located;

(B) Submit an application as provided by the Missouri Board of Pharmacy for licensure in compliance with 20 CSR 2220-2.020(2), (3), (9), and (10);

(C) Pay all appropriate licensing fees;

(D) Submit a copy of the state pharmacy license from the state in which the nonresident pharmacy is located;

(E) If controlled substances will be shipped into Missouri, submit a copy of the applicant’s federal controlled substance registration and, if applicable, a copy of the applicant’s state controlled substance registration from the state where the applicant is located;

(F) If the designated pharmacist-in-charge does not have a current and active Missouri pharmacist license issued by the board, submit an official verification from the state board of pharmacy or equivalent state pharmacist licensing agency verifying that the designated pharmacist-in-charge holds a current and active pharmacist license in the state in which the nonresident pharmacy is located; and

(G) Submit a copy of the applicant’s most recent pharmacy inspection by the applicant’s resident state board of pharmacy or its equivalent state regulatory body. The inspection must have occurred within the last eighteen (18) months for sterile compounding pharmacy applicants or within the last twenty-four (24) months for all other pharmacy applicants. If a state inspection is unavailable, an inspection by the Missouri Board of Pharmacy or from the Verified Pharmacy Program (VPP) of the National Association of State Boards of Pharmacy or a similar inspection by an entity approved by the board may be accepted.

(3) Each nonresident pharmacy shall supply any inspection reports, warning notices, notice of deficiency reports, or any other related reports requested by the board or the board’s authorized designee to review compliance with state and federal drug laws.

(4) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state that licenses and regulates nonresident pharmacies for the purpose of investigating complaints against pharmacies located in Missouri or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.
have occurred when—
1. The business is sold and the sale becomes final;
2. The proprietor enters into a partnership with another individual or business entity;
3. The proprietor dies, provided, the proprietor’s estate may continue to operate the third-party logistics provider or drug outsourcer facility for a period of no more than one (1) year if all appropriate fees are paid.

(B) If a corporation owns a third-party logistics provider or drug outsourcer, a new license is not required if the owners of the stock change. If a limited liability partnership or a limited liability company owns a third-party logistics provider or drug outsourcer, a new license is not required if the partners or members of the company change, as long as the partnership or company is not dissolved by the change. Written notice must be filed with the board within thirty (30) days after a change of twenty-five percent (25%) or more in the ownership of corporation stock, or the partners of a limited liability partnership, or the members of a limited liability company. The required notification must be in writing and notarized.

(C) When a sole proprietorship, corporation, limited liability partnership, or limited liability company begins or ceases ownership of a third-party logistics provider or drug outsourcer, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(3) Change of Location. A third-party logistics provider or drug outsourcer license is only valid for the address listed on the license issued by the board. If the location of a third-party logistics provider or drug outsourcer facility changes either within the existing facility or to a new facility, a change of location application must be submitted to the board with the applicable fee. A Missouri located facility may not open for business at the new location until the board or its duly authorized agent has inspected the premises of the new location and approved it. Once approved, the board will issue a license for the new location with the same license number as the previous license. A license will remain valid if the facility address changes but not the location, in such case an amended license will be issued on request without charge.

(4) Change of Name. Licensees may only conduct 3PL or drug outsourcing activities in the state of Missouri under the name(s) licensed by the board. If a name change occurs, a change of name application must be submitted to the board with the applicable fee within three (3) business days of the change. The facility’s license will be reissued under the new name with the same license number. A change of ownership application is required if the licensee is changing corporate or legal structure or otherwise changing ownership.

(5) Temporary Licenses. The board may grant a temporary license to an applicant, subject to any terms or conditions the board deems necessary or appropriate, to allow the business to continue operating in Missouri until the board makes a determination on the applicant’s license application. Unless otherwise authorized by the board, temporary licenses are valid for one (1) year or until final action by the board, whichever is less.

(A) The board will consider the following in determining whether to issue a temporary license:
1. Any conduct or activity that constitutes grounds for denial or discipline under section 338.055, RSMo;
2. The applicant’s compliance with state and federal drug and/or distribution laws;
3. Any failure to produce records or information requested by the board or failure to provide full and truthful information;
4. Failure to cooperate with any board request or inquiry related to the application;
5. Current or pending disciplinary action by any federal, state, or local government against any license or registration currently or previously held by the applicant;
6. Compliance with licensing requirements under previously granted licenses, if any; and
7. Any other factor relevant to the applicant’s ability to safely or properly operate in Missouri.

(B) A notification letter will be sent to the applicant once a decision is made on the applicant’s permanent license. The temporary license will be considered void ten (10) days after board notification is sent to the applicant.

(C) Applicants issued a temporary license may conduct business in this state as a third-party logistics provider or, for drug outsourcer applicants, as a drug outsourcer as long as all state and federal laws governing provider/drug outsourcing activities are followed and no action that results in professional misconduct as outlined in section 338.055, RSMo, occurs.

(6) A nonresident third-party logistics provider or drug outsourcer licensed by the board must designate a registered agent in Missouri for service of process. Any licensee that does not designate a registered agent shall be deemed to have designated the Missouri secretary of state to be its true and lawful attorney for service of process in any action or proceeding against the third-party logistics provider or drug outsourcer growing out of or arising from such 3PL or drug outsourcing services. Service of process shall be accomplished as authorized by law.

(7) Licensure Exemptions. A Missouri 3PL or drug outsourcer license is not required for the following activities—

(A) The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, transfer, or trade a drug for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. Prior to the distribution, the unlicensed entity or proposed recipient must file a written request with the board to approve the emergency transaction. The amount sold, purchased, transferred, or traded shall not exceed one percent (1%) of the 3PL’s or drug outsourcer’s total gross prescription sales or, if prescriptions are not sold, one percent (1%) of the 3PL’s/drug outsourcer’s total drug purchases;

(B) The storage or distribution of drugs by a local, state, or federal facility that are received from the Strategic National Stockpile or the state stockpile for the purpose of providing those drugs in an emergency situation as authorized by a state or federal agency; and

(C) The sale, purchase, transfer, or trade of a prescription drug by a 3PL to alleviate a temporary shortage of a prescription drug that is in limited supply or unavailable due to delays in or interruption of supply. Drugs sold, purchased, transferred, or traded pursuant to this section shall only be sold, purchased, transferred, or traded directly from an importer or manufacturer authorized by or registered with the United States Food and Drug Administration (FDA) to import or manufacture the drug that is unavailable or in short supply. In addition, sales, purchases, transfers, or trades shall be limited to the period of shortage and to the drug that is unavailable or in limited supply. Documentation of FDA authorization or registration shall be maintained in the 3PL’s records.

PURPOSE: This rule establishes additional guidelines for non-resident third-party logistics providers and drug outsourcer applicants.

EMERGENCY STATEMENT: The Missouri General Assembly recently enacted HB 1719 which establishes new licensure classifications for third-party logistics providers (3PL) and drug outsourcers. The new law is effective August 28, 2018, and would prohibit non-resident third-party logistics providers and drug outsourcers from operating in Missouri without the required license. These entities currently provide needed prescription medication to Missouri hospitals, pharmacies, and health care providers. In some instances, the medications may not be available from another source qualified under federal law to provide the medication. In other instances, medication may be needed for emergency use. HB 1719 does not allow a grace period for licensure. Accordingly, this rule would establish provisions for the immediate licensure of non-resident 3PLs and drug outsourcers.

The board has determined an emergency rule is needed to protect the lives and health of Missouri citizens by ensuring the continued availability and supply of prescription drugs in this state via non-resident 3PLs or drug outsourcers. Absent an emergency rule, non-resident 3PLs and drug outsourcers would be required to terminate activities which would significantly and detrimentally impact Missouri’s drug supply, including, the availability of medication for emergency use. Significantly, purchasing medication from an unlicensed 3PL or drug outsourcer is a criminal offense. As a result, the Missouri State Board of Pharmacy finds there is an immediate danger to the public health, safety, and/or welfare and a compelling governmental interest that requires this emergency action. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Missouri State Board of Pharmacy believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed November 28, 2018, becomes effective December 8, 2018, and expires June 5, 2019.

(1) Nonresident third-party logistics (3PL) providers or drug outsourcer facilities may not act as a third-party logistics provider or a drug outsourcer or ship, mail, or deliver legend drugs, or for drug outsourcers, compounded drugs into Missouri without first obtaining the applicable license from the board. Nonresident third-party logistics providers or drug outsourcers may be licensed by reciprocity if they:

(A) Possess a valid 3PL or drug outsourcer license or an equivalent license that is in good standing in the state or foreign jurisdiction in which are located that was issued pursuant to legal standards comparable to those which must be met by a Missouri third-party logistics provider or drug outsourcer; and

(B) Are located in a state or foreign jurisdiction which extends reciprocal treatment to a third-party logistics provider of this state or, for drug outsourcer applicants, a drug outsourcer of this state.

(2) Except as otherwise provided in this rule, applicants for a nonresident third-party logistics provider or drug outsourcer license must comply with 20 CSR 2220-8.020, including, but not limited to, all application, change of ownership, change of location, and change of name requirements. In addition to the requirements of 20 CSR 2220-8.020, non-resident applicants must also submit the following with their application:

(A) A copy of the applicant’s 3PL or drug outsourcer license or its equivalent from the state or foreign jurisdiction where the nonresident third-party logistics provider or drug outsourcer facility is located;

(B) An official verification from the state or foreign jurisdiction where the third-party logistics provider or drug outsourcer facility is located verifying that the applicant holds a current and active third-party logistics provider license or its equivalent, for drug outsourcer applicants, a drug outsourcer license or its equivalent issued by such state or foreign jurisdiction;

(C) A copy of the applicant’s most recent inspection report or findings from the applicant’s resident board of pharmacy or its equivalent state/foreign regulatory body. For 3PL applicants, the inspection must have occurred within the last twenty-four (24) months. For drug outsourcer applicants, the inspection must have occurred within the last eighteen (18) months. If a state inspection is unavailable, an inspection by the Missouri Board of Pharmacy, the United States Food and Drug Administration (FDA) or the National Association of State Boards of Pharmacy must be submitted or a similar inspection by an entity approved by the board;

(D) If controlled substances will be shipped into Missouri, a copy of the applicant’s federal controlled substance registration and, if applicable, a copy of the applicant’s state controlled substance registration from the state where the applicant is located; and

(E) If requested by the board, any inspection reports, correction active responses, warning notices, deficiency notices, or any other related state, federal, or foreign jurisdiction report or notice related to the applicant’s handling, distribution, manufacturing, or sale of medication.


Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 8—Third-Party Logistic Providers and Drug Outsourcer Facilities

EMERGENCY RULE

20 CSR 2220-8.040 Standards of Operation (Drug Outsourcers)

PURPOSE: This rule provides standards of operation for drug outsourcers licensed by the board.

EMERGENCY STATEMENT: The Missouri General Assembly recently enacted HB 1719 which establishes a new license classification for drug outsourcers, effective August 28, 2018. The board has simultaneously filed emergency rules to license drug outsourcers. Drug outsourcers are authorized by federal law to engage in sterile compounding which is the act of compounding a drug that must be sterile and free of harmful microorganisms prior to administration to a patient. Sterile compounding requires the use of aseptic techniques in a properly controlled environment to eliminate the risk of preparation contamination. The United States Food and Drug Administration has indicated: “Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compound drug products are not FDA-approved which means they have not undergone FDA premarket review for safety, effectiveness, and quality.”

In 2012, the FDA reported that a Massachusetts sterile compounding facility shipped contaminated injectable drug products to patients and healthcare practitioners that caused a nationwide fungal meningitis outbreak that resulted in more than sixty (60) deaths and seven hundred fifty (750) cases of infection. Since 2012, the FDA reported it has “investigated numerous outbreaks and other serious adverse events, including deaths, associated with compounded drugs that were contaminated or otherwise compounded improperly” since the fungal meningitis outbreak.
9. Rx Cares for Missouri Patient Counseling Educational Campaign
10. **Approval of Special Sites/Non-Pharmacist Preceptors** (*= new applicant)
   a. Battle Creek Veterans Affairs Medical Center*
   b. Veterans Affairs of St. Louis Health Care System- Washington Community Based Outpatient Clinic*
   c. CVS Pharmacy Business Management*
   d. EPI-Q, Inc.*
   e. Haskell Indian Health Center*
   f. Maternal Fetal Care Center at SSM Health St. Mary’s*
11. Executive Director Office Updates