MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

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

September 9, 2020
3:00 p.m.

Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 3:00 p.m. on September 9, 2020 via conference call. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he may join the WebEx meeting by:

1) Joining online at:
   https://stateofmo.webex.com/stateofmo/j.php?MTID=m3a1c1f243acc23f2c838dc6723ea4769
   Access Code: 133 157 1171
   Password: MWgpxp9PD73

2) Calling:
   Phone #: 650-479-3207
   Access Code: 133 157 1171
   Password: MWgpxp9PD73

****Public participants may be required to provide a name and e-mail address when joining the WebEx meeting online. NEW: A password may also be required when joining the meeting (provided above). WebEx will provide a conference call phone number to access the audio portion of the call after you join. Telephone charges may apply as assessed by your service provider. ****

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) and (14) and section 324.001.8 and .9, 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

September 9, 2020
3:00 p.m.

OPEN SESSION AGENDA

#1. Call to Order: James Gray, RPh, President

#2. Roll Call

#3. Approval of Minutes
   a. May 13, 2020
   b. May 19, 2020

#4. COVID-19 Updates
   a. Office Updates
   b. Waiver Updates
   c. NABP Updates
   d. CDC/FDA Updates
   e. COVID-19 Vaccines/COVID-19 Testing

#5. 2020 Legislative Implementation
   a. Class R Remote Dispensing Pharmacy Update
   b. HB 2046/Fresh Start Act

#6. FDA Compounding MOU
   a. FDA Updates
   b. Rule Discussion Draft

#7. UMKC School of Pharmacy/STLCoP Annual School Meeting
   a. UMKC School Update
   b. STLCOP School Update
   c. Board discussion/Q&A
   d. Review of special site/non-pharmacist preceptor lists.

#8 20 CSR 2220-2.120 Transfer of Prescription or Medication Order Information
   a. Discussion draft amendment

#9. General Office Updates

e. Office Updates
f. Licensing Updates
g. Rule Update/Future Rule Review Planning
h. 2021 Legislative Updates
i. Budget Updates
j. Rx Cares for Missouri Medication Disposal

#10. Future Meeting Dates/Topics

a. Proposed Meeting Dates/Times

#11. Adjournment

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy may go into closed section pursuant to Section 610.021(1) and (14) and section 324.001.8 and .9, 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.

#3. Approval of Minutes

a. May 13, 2020
b. May 19, 2020

OPEN SESSION MINUTES

Missouri Board of Pharmacy
CONFERENCE CALL

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

May 13, 2020
1:00 p.m.

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
Douglas R. Lang, R.Ph., President
James Gray, PharmD., Vice-President
Colby Grove, PharmD., Member
Christina Lindsay, PharmD., Member
Pamela Marshall, R.Ph., Member
Christian Tadrus, PharmD., 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
Lisa Everett, R.Ph, Inspector
Kim Hatfield, Pharmacist Coordinator

Others Present
Daryl Hylton, Legal Counsel

President Douglas Lang called the meeting to order at approximately 1:04 p.m. on May 13, 2020, and roll call was taken.

#3. Approval of Minutes
a. March 11, 2020

A motion was made by Christian Tadrus, seconded by Anita Parran, to approve the March 11, 2020, minutes. Motion passed 6:0:0:0 by roll call vote as follows:

Colby Grove – Yes	**James Gray- Yes**	**Christina Lindsay- Yes**
Pamela Marshall – Yes	**Anita Parran – Yes**	**Christian Tadrus- Yes**

#4. COVID-19/Emergency Response Updates

a. Office/Status Update

DISCUSSION: Kimberly Grinston provided the following updates:

- Board staff is back in the office as of May 4, 2020; however, staff is staggering working days to ensure social distancing. Phones are being answered and additional temporary staff will be helping with clerical work.
- Staff is conducting an after action review to evaluate successes, challenges and best practices from the COVID-19 shutdown; Additional information will be provided at the next strategic planning meeting.
- DHSS asked the Board to send an e-alert to pharmacists and pharmacies regarding CLIA waivers and COVID-19 testing. However, the FDA will be meeting with the 50 states and NABP on Friday to discuss COVID-19 testing. The requested e-alert will be held until after the FDA meeting. In the interim, a COVID-19 testing resource page will be added to the Board's website.

b. Licensing Updates

DISCUSSION: Kimberly Grinston commended board staff for doing an exemplary job maintaining board operations while the office was closed. Ms. Grinston reported the pharmacy technician desk decreased application processing times during the closure and the Board had one of its lower average application issuance rates. Ms. Grinston provided the following additional information:

- Pearson Vue (testing company) has opened some test centers throughout the state, including contracted facilities; however, testing facilities will be operating at 50% capacity. Pearson Vue will be prioritizing requests for the healthcare exams, which would include pharmacy.
- Staff issued guidance to Missouri pharmacy students on applying early for pharmacist licensure to secure a faster testing date. Due to the expedited application procedures, 97% of all new applications from Missouri school graduates are granted ATT within 48 hours. Board staff has met with Kansas University and Southern Illinois University-Edwardsville, and will begin taking electronic applications from their students on May 15, 2020.
- Fingerprinting sites may still be closed or have limited office hours due to COVID-19. As a result, the office is processing exam applications and granting authorization to test (ATT) prior to applicants being fingerprinted to allow students to secure an earlier testing date. Licenses will not be finally approved and issued until the Board receives fingerprint results.
- NABP will not allow students to take the NAPLEX remotely but is considering

remote proctoring of the MPJE. Students remotely taking the MPJE will be visually monitored by an approved testing proctor electronically and the candidate's computer system will need to be cleared by NABP prior to the exam. NABP anticipates students will be able to remotely take the MPJE on demand beginning July 1st.

- NABP is requiring a transcript for all new graduates this year; Test scores will not be released before NABP receives the transcript. The Board office is not requiring transcripts, however, the office is accepting electronic verification of graduation/intern hours from Missouri schools provided the verification comes directly from the school and from a Board approved/recognized e-mail address.
- The pharmacy technician expiration date has been extended through July 31st. The Division may not be able to mail postcard reminders due to COVID-19 and limited staffing, however, an e-mail notification will be sent to technicians that haven't renewed.
- The University of Missouri-Kansas City (UMKC) and St. Louis College of Pharmacy (STLCOP) requested the Board lift the maximum weekly limit for intern hours; The topic will be included on the next agenda to meet Sunshine Law requirements. Ms. Grinston reported some of the intern practice sites have closed or cancelled intern participation due to COVID-19, and the schools asked the Board to extend the weekly limit on intern hours to allow students to make up hours and to accommodate alternate preceptor schedules (e.g., preceptors working 7 days on, 7 days off). Ms. Grinston noted ACPE does not have a limit on weekly intern hours.

Douglas Lang asked how many pharmacy technicians have renewed; Kimberly Grinston indicated approximately 52% have renewed which is consistent with the Board's normal averages. Ms. Grinston stated staff will continue communicating with technicians who have not renewed.

c. Inspector Updates

DISCUSSION: Kimberly Grinston reported inspections have resumed; Inspectors will be asking COVID-19 risk assessment questions prior to entering a pharmacy. Inspectors will also be wearing masks and gloves during inspections and will be limiting inspections of high-risk sites.

- Douglas Lang asked if the revised COVID-19 inspection plans will impact annual inspections of sterile compounding pharmacies and the regular inspection schedule. Tom Glenski replied inspectors were out of the field for six (6) weeks due to COVID-19 so inspection numbers will be lower than previous years, which could impact inspection timeframes.

d. Statutory/Rule waivers

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

- The Governor's office has extended the approved COVID-19 waivers through June 15, 2020, however, agencies have been advised they can expire waivers, if deemed necessary or appropriate.
- The Missouri Hospital Association (MHA) asked the Board to continue the waivers that accommodate FDA allowances for hospitals and hospital compounding. MHA forwarded their request to the Governor's office.
- The remote data entry waiver ends June 15, 2020; however, the Board's remote data entry rule will not be effective until the middle of August. Ms. Grinston suggested the Board discuss how to educate licensees on phasing out the remote data entry waiver until the new rule is effective.

Douglas Lang suggested asking the Governor's office to extend the remote data entry waiver for an additional 60-days to bridge the gap between the waiver and the pending remote data entry rule. Mr. Lang stated switching business operations requires a significant amount of work and planning and noted many employers are still limiting the number of office staff due to COVID-19. Christian Tadrus questioned if an emergency rule could be filed to address the gap between the remote data entry waiver and the pending rule and asked if staff had data on how many licensees are using the waiver. Staff stated no data is currently available.

Pamela Marshall suggested the Board take appropriate action to prevent a gap in the remote data entry allowance given COVID-19 and the potential health threat. Additional Board discussion held; Board consensus to request an extension of the remote data entry waiver until the rule is effective.

Christian Tadrus suggested the Board ask to extend all waivers that accommodate federal allowances and asked how other states are handling waiver requests. Kimberly Grinston indicated staff could contact border states for feedback; Douglas Lang stated Tennessee extended their emergency order for remote data entry an additional 45 days.

Christian Tadrus questioned if bordering states had waivers that focused on patient care activities such as ordering/administering tests, and asked if the Board should take action to allow pharmacist COVID-19 testing. Kimberly Grinston stated the Board took the position that testing was not prohibited by Chapter 338; therefore, the Board did not seek waivers for testing,

Daryl Hylton noted the waivers were issued as part of the Governor's authority during a declared State of Emergency and suggested the Governor may need to extend the state of emergency in order to extend the waivers.

#5. 2020 Legislative Update

- Legislative Summary Chart
- HB 1511 (Military Spouses/Reciprocity)
- HB 1682 (Charitable Pharmacy)

DISCUSSION: Kimberly Grinston provided the following updates:

- The legislative session ends on May 15, 2020. Session was temporary suspended due to COVID-19, and legislators are trying to get their high priority bills passed before session ends.
- HB1682 includes Senator Sater's remote dispensing site language. Ms. Grinston asked Senator Sater to remove the language and to revisit remote dispensing after pilot project data has been collected/reviewed. Senator Sater declined to remove the language; Similar remote dispensing language has been added to SB673.
- HB 1682 includes the new Class Q (Charitable Pharmacy) classification; however, the Board was able to remove the proposed Class Q definition.
- Staff continues to voice concerns/objections to HB2046 which would require licensing Boards to list all crimes that would prohibit someone from obtaining a license.

Douglas Lang asked for a status update on HB1693 (PDMP). Ron Fitzwater replied HB1693 is on the house floor; however, legislators removed the fentanyl language. Mr. Lang asked about SB689 which limits Board expenditures for continuing education. Kimberly Grinston noted HB2046 still includes the continuing education restriction, however, language has been added that would allow boards to use fees to educate licensees on rules/policies. Ms. Grinston reported HB2046 was passed and is pending the Governor's signature.

Douglas Lang asked about the status of SB928 (controlled substances shipped to a physician's office) and HB1410 (HIV/PREP). Ron Fitzwater noted the language from SB928 was added to HB1682 but no action has been taken on HB1410.

#6. Petition to Amend 20 CSR 2220-2.010(1)(D)

- Animal Policy Group Rule Petition
- Reference Flyer

DISCUSSION: Kimberly Grinston stated the Board has been asked to amend 20 CSR 2220-2.010(1)(D) to require veterinary reference materials for pharmacies dispensing veterinary medication. Ms. Grinston noted the Board is not required to amend the rule; however, a response must be filed with JCAR and the Office of Administration indicating the Board's intention.

Board discussion held on the draft response included in the agenda; Board members noted pharmacies dispense multiple types of medication and suggested requiring a different reference for each medication category may be burdensome and costly. Board members suggested reviewing reference requirements as part of the Board's overall review of 20 CSR 2220-2.010. Board consensus not to amend the rule at this time and to approve the draft response provided by the Executive Director.

#7. Approval of Special Sites/Non-Pharmacist Preceptors

a. Lumeris Healthcare Outcomes, LLC (Renewal)

Tom Glenski recommended approving the special site. **A motion was made by Pamela Marshall, seconded by Christina Lindsay, to approve Lumeris Healthcare Outcomes, LLC renewal for 500 hours. Motion passed 6:0:0:0 by roll call vote as follows:**

Colby Grove – Yes	**James Gray- Yes**	**Christina Lindsay- Yes**
Pamela Marshall – Yes	**Anita Parran – Yes**	**Christian Tadrus- Yes**

#8. Executive Director Office Updates

a. General Office Updates
b. Rule status report
c. Licensing/Renewal updates
d. NABP Update
e. Rx Cares for Missouri Update

DISCUSSION: Kimberly Grinston provided the following updates:

1. The revised multi-med pak rule and amended military spouse rule will be effective on May 30, 2020.
2. The revised intern rules will be effective July 30, 2020; however, Missouri schools are already complying with the rules as part of the Board's approved COVID-19 accommodations.
3. The remote data entry and technician supervision rule will likely be effective at the end of August, as previously discussed.
4. The Board's revision to the return and reuse rule was approved by the Department today and will be sent to the Secretary of State's office.
5. The comment period on the proposed tobacco cessation prescribing rule will close on May 15, 2020; Comments will be provided at the next meeting.
6. The pharmacist and pharmacy intern renewal fee decrease is still pending. Board staff does not anticipate problems obtaining approval.
7. FDA released their latest draft of the state Memorandum Of Understanding (MOU) regarding pharmacy compounding; Staff has been informed FDA will likely adopt the recent MOU without changes. Legal counsel and staff are reviewing the MOU and will provide comments/updates at the next meeting.

MOTION FOR CLOSED SESSION (2:13 P.M.)

A motion was made by Colby Grove, seconded by Pamela Marshall, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from the closed meeting be closed under Section 610.021(1) and (14), RSMo, and 324.001.8 and 324.001.9, RSMo. Motion passed 6:0:0:0 by roll call vote as follows:

Colby Grove – Yes	**James Gray- Yes**	**Christina Lindsay- Yes**
Pamela Marshall – Yes	**Anita Parran – Yes**	**Christian Tadrus- Yes**

RETURN TO OPEN SESSION

By motion duly made and recorded in the closed session open session minutes, the Board returned to open session at approximately 3:17 p.m.

MOTION TO ADJOURN (3:18 P.M.)

A motion was made by Pamela Marshall, seconded by James Gray to adjourn the May 13, 2020, conference call. Motion passed 4:0:0:2 by roll call vote as follows:

Colby Grove – Absent	**James Gray- Yes**	**Christina Lindsay- Absent**
Pamela Marshall – Yes	**Anita Parran – Yes**	**Christian Tadrus- Yes**

THE MEETING WAS ADJOURNED AT 3:18 P.M.

_____

KIMBERLY GRINSTON
EXECUTIVE DIRECTOR

OPEN SESSION MINUTES

Missouri Board of Pharmacy
CONFERENCE CALL

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

May 19, 2020
3:00 p.m.

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
Douglas Lang, R.Ph., President
James Gray, PharmD., Vice-President
Christian Tadrus, PharmD, Member
Pam Marshall, R.Ph., Member
Colby Grove, PharmD., Member
Christina Lindsay, PharmD., 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
Lisa Everett, R.Ph., Inspector
Elaina Wolzak, R.Ph., Inspector

Others Present
Daryl Hylton, Legal Counsel
Sarah Ledgerwood, Interim Division Director

OPEN SESSION
By motion duly made and recorded in the closed session minutes, the Board convened in open session at approximately 3:17 p.m. President Douglas Lang called the meeting to order at approximately 3:21 p.m. on May 19, 2020, and roll call was taken.

#3. COVID-19/Emergency Response Updates

a. Expiration of State of Emergency

DISCUSSION: Kimberly Grinston reported a request was sent to the Governor's office to continue the pharmacy related COVID-19 waivers after the State of Emergency expires, as requested by the Board. Ms. Grinston stated no response has been received from the Governor's Office at this time and suggested the Board may be able to expedite the Governor's review by identifying specific waivers the Board would like to continue.

b. Office/Status Update

DISCUSSION: Kimberly Grinston reported staff is still rotating between the office and working remotely. Ms. Grinston stated the Board office received over 100 pharmacist exam applications over the weekend and staff is granting authorization to test (ATT) within approximately 48 hours under the expedited application procedures.

c. Licensing Updates

DISCUSSION: Kimberly Grinston stated St. Louis College of Pharmacy and University of Missouri-Kansas City asked the Board to modify 20 CSR 2220-7.025(4)(C) to remove or increase the current maximum limit of 48 intern hours per week. Ms. Grinston indicated several intern sites have reportedly cancelled/restricted access due to COVID-19 and students may need additional hours to complete graduation requirements.

James Gray questioned if the rule could be amended in time for the 2020-2021 school year; Ms. Grinston advised the rulemaking process normally takes 6-8 months and estimated the rule change would not be effective until early 2021 under best case scenario. Douglas Lang suggested the Board request a waiver to extend the intern hour limit if the Governor declares another State of Emergency. Pamela Marshall noted the schools mentioned students working with preceptors who are doing 7-hours on/7-hours off shifts, however, Ms. Marshall noted these shifts are usually overnight and questioned how much quality time the intern would be spending with the preceptor.

Board consensus to table amending the rule at this time since the rule cannot be finalized in time for the 2020-2021 school year; Further consensus to discuss the limit on intern hours at a future meeting.

d. Inspector Updates

DISCUSSION: Kimberly Grinston reported inspections have resumed with a modified schedule. Ms. Grinston stated inspectors will be wearing gloves and masks during the inspection and requested that pharmacy staff maintain social distancing while the Inspector is on-site.

e. *Statutory/Rule waivers*

1. 5/1/20 Approved Waiver list

DISCUSSION: Board discussion held on the COVID-19 waiver expiration guidance provided by the Executive Director for release by the Board; Approved changes are included in Attachment A. Board members asked staff to clearly communicate that the pharmacy technician renewal waiver does not expire and technicians still have until July 31, 2020, to renew.

Douglas Lang asked Board members to review the current approved waiver list as previously suggested by the Executive Director, and identify specific waivers the Board would like to remain in effect after the State of Emergency expires. The following Board discussion was held:

1. Technician renewals: Board consensus to request a waiver extension.
2. § 338.020 (Unlicensed practitioners): Kimberly Grinston reported only 17 people have filed an emergency practice application. Board consensus not to request a waiver extension.
3. § 338.056 (Albuterol inhaler substitution): James Gray stated hospitals are not treating COVID-19 patients with inhalers as much as they were when the pandemic began and suggested hospitals may have a sufficient supply. Christian Tadrus noted Missouri did not have as many COVID-19 cases as originally anticipated. Board consensus not to request a waiver extension.
4. § 338.200.1 (Emergency dispensing): Board consensus not to request a waiver extension.
5. § 338.220 (Class J activities): Douglas Lang noted the federal waiver related to sterile compounding for hospitalized patients may address some of the initial Class J concerns; Board consensus not to request a waiver extension.
6. 20 CSR 2.010(1)(A) (Pharmacy technicians/pharmacy interns dispensing medication without a pharmacist present): Board consensus not to request a waiver extension.
7. 20 CSR 2220-2.010(1)(B) (Remote product verification): James Gray stated this waiver has been helpful for hospitals because pharmacists are working from home to prevent becoming ill. Christian Tadrus questioned if the waiver was needed for all pharmacies. Board consensus to request a waiver extension just for hospitals.
8. 20 CSR 2.200(10)(B) (Sterile compounding/Aseptic skill assessment): James Gray stated this waiver is also helpful for hospitals that may need to move staff around the system/facility. Board consensus to request a waiver extension.
9. 20 CSR 2220-2.400(9) (Missouri pharmacies compounding commercially available products for hospitals): Douglas Lang noted the Missouri Hospital Association asked to maintain this waiver. Board consensus to request a waiver extension.
10. 20 CSR 2220-2.400(12) (Distribution of compounded preparations by hospital pharmacies without a patient-specific prescription): Board consensus to

request a waiver extension.

11. 20 CSR 2220-2.200(14) (Compounding medication for hospitalized patients pursuant to FDA guidance): Board consensus to request a waiver extension.
12. 20 CSR 2220-2.650 (Class-J Shared Services): Douglas Lang stated this waiver was partially intended to assist hospitals and asked if the waiver was necessary for entities sharing services that are under common ownership; Tom Glenski suggested the waiver is unnecessary. Board consensus not to request a waiver extension.
13. Remote data entry: Douglas Lang noted the remote data entry rule will be effective shortly and expressed concerns with forcing licensees to transition employees back to the office during COVID-19. Board consensus to request a waiver extension.

Kimberly Grinston reported the FDA issued guidance for pharmacists administering COVID-19 testing which will be added to the Board's online resource page; Christian Tadrus suggested the Board add a note on the online page that the listed resources do not include all available resources that may be helpful.

#4. 2020 Legislative Update

a. TAFP bills

DISCUSSION: Kimberly Grinston provided a list of bills that were Truly Agreed and Finally Passed and provided the following bill summary:

- HB1682 includes charitable pharmacy language, remote dispensing language, and language that allows pharmacies to dispense controlled substances to a practitioner's office. Ms. Grinston noted the controlled substance language would align BNDD's regulation with DEA regulations.
- HB1896 reclassifies controlled substances and pseudoephedrine.
- HB2046 adds a Class Q charitable pharmacy permit class; The charitable pharmacy definition and donation allowance was removed from the final bill.

Douglas Lang noted HB1682 expands stocking/use of epinephrine for qualified first responders and suggested updating the practice guide.

#5. Final Order of Rulemaking 20 CSR 2220-6.200 (Pharmacist Authority to Prescribe)

a. Proposed Rule (4/15 Register)
b. Section 338.665
c. Comments

DISCUSSION: Kimberly Grinston stated the comment period on the proposed rule closed on May 15, 2020; The Board received comments from the Missouri Pharmacy

Association (MPA), National Association of Chain Drug Stores (NACDS), and G.L.O. & Associates. Ms. Grinston stated the Board of Healing Arts is meeting on May 31, 2020, to review comments and any changes from the Board would need to be provided before their May 31st meeting. The following discussion was held:

- Ms. Grinston stated NACDS asked to remove the requirement that pharmacists maintain ongoing/continued competency. Pamela Marshall suggested pharmacists should be required to maintain training for the specific drugs they will be prescribing. Board consensus not to amend the competency requirement.
- Kimberly Grinston noted CVS and NACDS suggested the rule allow an intern and technician to collect patient medical histories; Ms. Grinston stated this would be allowed under current Board rules. Board consensus not to modify the rule as suggested.
- Kimberly Grinston stated NACDS suggested the Board amend section (4) by deleting the list of minimum required components for documentation of patient services. Ms. Grinston stated the Board originally wanted pharmacists to be treated like other healthcare professionals and staff mirrored the documentation language required for nurses and physician assistants. Board consensus not to modify the rule as suggested.
- Kimberly Grinston stated MPA and G.L.O. suggested the rule require pharmacists to document the time the patient was seen because billing entities may require it. Ms. Grinston indicated the Board asked to adopt a standards of practice approach and not to be proscriptive in the rule. Board consensus not to modify the rule as suggested. Christian Tadrus suggested including the time documentation and billing issue in future Board guidance.
- Kimberly Grinston stated MPA and G.L.O. suggested modifying the rule to require documentation of the patient's primary care provider "if determined." Tom Glenski noted the administration rules use "if provided" which is consistent with the Board's intent for the current rule. Mr. Glenski noted the pharmacist would be the prescriber of record and would not have to notify anyone of the therapy. Board consensus to require documentation of the primary care provider "if provided."
- Kimberly Grinston stated MPA and G.L.O. asked the Board to amend section (2) to require that pharmacists obtain a Board certificate of medication therapeutic services (MTS) to prescribe pursuant to § 338.665, RSMo. Kimberly Grinston noted the Board previously discussed the suggestion and decided not to include requirements that were stricter than statute. Ms. Grinston also suggested the change may be construed as substantive which cannot be done in the final order of rulemaking. Board consensus not to amend the rule at this time but to consider MTS certification at a future meeting.

Additional Board discussion held on the proposed final order of rulemaking included in the agenda; **A motion was made by Christian Tadrus, seconded by Pamela Marshall, to accept 20 CSR 2220-6.200 as amended for final rule making and to**

approve the final order of rulemaking as reflected in Attachment B. Motion passed 6:0:0:0 by roll call vote as follows:

Colby Grove – Yes	**James Gray- Yes**	**Christina Lindsay- Yes**
Pamela Marshall – Yes	**Anita Parran – Yes**	**Christian Tadrus- Yes**

#6. 2021 Proposed Legislation

a. Pharmacy quality assurance/quality improvement (QA/QI)
b. Pharmacy technician training & education
   1. Capstone Institute
c. Pharmacist scope of practice
d. Pharmacist testing & administration services (e.g., POC testing)
e. Recognition of pharmacies as health care entities
f. Permit holder accountability
g. Ensuring pharmacist involvement in medication dispensing
h. Pharmacist access to patient medical records
i. E-prescribing for all prescriptions
j. Consolidation of pharmacist protocol authority
k. Board members as preceptors
l. DHSS authorization of statewide protocols for pharmacist activities
m. Pharmacist prescriptive authority for oral contraceptive pills

DISCUSSION: Douglas Lang noted the list of proposed legislation includes items Board members previously asked to discuss. Mr. Lang noted the Executive Director has been advised the Governor's Office will likely focus on items that will create jobs and save money and may not approve proposals with significant fiscal costs to the state or the public. The following Board discussion was held:

- Pamela Marshall and Douglas Lang expressed support for pursuing the Quality Assurance/Quality Improvement (QA/QI) proposal. Ms. Marshall suggested the QA/QI language should also address pharmacy technician training. Christian Tadrus questioned if the QA/QI requirement would be different in a community, hospital, or mail order setting. Mr. Hylton noted the proposal would apply to all licensees and would allow each licensee to independently establish a compliant QA/QI program.
- Board members asked if the Board should have access to QA/QI records and questioned how federal patient safety organization (PSO) laws might impact document access. Mr. Hylton stated information reported to a federal PSO would be privileged and not available to the Board; however, information maintained as part of the Board's QA/QI program could be accessed if required by statute. Douglas Lang noted some states do not have access to QA/QI records but have access to a summary of QA/QI reports. Mr. Lang suggested potential QA/QI language should include mandatory reporting within fifteen (15) days if a QA/QI event caused a death or hospitalization.
- Pamela Marshall stated pharmacy technician training/education is still an

important patient safety issue although previous legislative proposals have not been approved. Ms. Marshall indicated she asked representatives from Capstone Institute to present information regarding their pharmacy technician training program to provide ideas on the types of training programs that are available. Ms. Marshall introduced Avril Gordon who provided the following information:
  - Capstone Institute is an online pharmacy technician training program that has been operating since 2017.
  - Capstone's goal is to enhance patient safety with a specific emphasis on drug knowledge and training; The program has graduated over fifty (50) students. In addition to enhanced training, pharmacy technicians are paired with professionals to prepare them for national technician certification.
  - The Pharmacy Technician Certification Board (PTCB) requires training at an approved school and Capstone Institute is an approved school.
- Pamela Marshall noted Capstone is a good example of a standardized training program that the Board should consider.

Board consensus to survey Board members to determine which legislative items Board members would like to pursue in 2021.

#7. Draft/Suggested Rule Revisions
   a. Drug Utilization Review/Revision of 20 CSR 2220-2.195
   b. 20 CSR 2220-2.120 (Transfer of Rx or Medication Order Information)
   c. 20 CSR 2220-2.900 (Automated Dispensing and Storage Systems)

DISCUSSION: Due to time constraints, Board consensus to table this item until the June conference call.

#8. Executive Director Office Updates
   a. FDA Memorandum of Understanding (MOU)- Certain Distribution of Compounded Human Drug Products

DISCUSSION: Douglas Lang noted staff is reviewing the MOU and will bring back comments and suggestions at a future meeting. Kimberly Grinston provided the following updates:

- The FDA hosted a virtual meeting on the MOU for the states and NABP; The FDA will be taking informal comments on the MOU but informed states the document will not be substantively revised. States will have 1-year to sign the MOU once the final document has been issued which should be in July.
- NABP recognized the MOU is not perfect but believes the document protects patients and the states and strongly suggested the states sign.

Daryl Hylton said he will provide a legal review of the MOU at a future meeting; Kimberly Grinston asked Board members to e-mail any comments, concerns or

questions on the MOU to her attention.

Add'l Office/Bd Updates

Ms. Grinston provided the following updates:

- The Board's proposed renewal fee decrease for interns and pharmacists is still pending with the Governor's Office. Ms. Grinston noted the fee decrease may not be top priority given the pressing state COVID-19 issues.
- Ms. Grinston and President Lang attended NABP's virtual annual meeting. New officers were elected and Carmen Catizone ended his term as NABP Executive Director. Al Carter will serve as the new Executive Director of NABP. Ms. Grinston will add approved NABP resolutions to the June conference call.
- 503(b) Inspection Program: Tom Glenski provided the following information:
    - Daniel Vandersand and Katie DeBold assisted in preparing a 503(B) inspection guide, inspection form and a document request form, which was included in the Board's agenda materials. Mr. Vandersand attended a four (4) week FDA 503B inspector training program which also included 40 hours of at-home study. The proposed inspection documents are similar to the FDA's inspection system.
    - Board inspectors will be testing the inspection documents during upcoming drug outsourcer inspections that Mr. Vandersand and Ms. DeBold will be conducting jointly.
    - Douglas Lang asked if the inspection observations should align with the document request form; Tom Glenski stated the inspectors thought the inspection form was a better approach based on FDA's inspection model. Mr. Glenski noted the document request form was shared with two of Missouri's outsourcers for feedback.
    - Board members commended Tom Glenski, Dan Vandersand and Katie DeBold for their work on the inspection documents.

MOTION TO ADJOURN (5:33 P.M.)

A motion was made by Pamela Marshall, seconded by Anita Parran to adjourn the May 19, 2020, conference call. Motion passed 6:0:0:0 by roll call vote as follows:

Colby Grove – Yes	**James Gray- Yes**	**Christina Lindsay- Yes**
Pamela Marshall – Yes	**Anita Parran – Yes**	**Christian Tadrus- Yes**

THE MEETING WAS ADJOURNED AT 5:33 P.M.

_____
KIMBERLY GRINSTON
EXECUTIVE DIRECTOR

MISSOURI BOARD OF PHARMACY
COVID-19 WAIVER UPDATE
(5-20-20)

This has been an unprecedented time for our state and the pharmacy profession. We appreciate all of the Board's licensees and registrants who have risen to the occasion and taken extraordinary steps to take care of Missouri's patients.

Governor Parson has announced implementation of the "Show Me Strong Recovery" plan which outlines steps for gradually and safely reopening Missouri's economy and social activity. As we move past the initial phase of the State of Emergency, the Governor's office has announced the emergency licensing/regulatory waivers issued pursuant to Executive Order 20-04 **will expire on June 15, 2020**.

In line with the Governor's directive, the pharmacy statutory/regulatory waivers listed in Attachment A will **terminate at midnight on June 15, 2020**. Licensees should begin taking steps to return to normal operational procedures after June 15th.

- The Board recognizes that COVID-19 response efforts are still ongoing. The Board is in the process of requesting approval to extend those waivers that may still be needed during the pandemic, including, waivers issued to accommodate federal COVID-19 allowances/guidance statements (e.g., FDA, CMS). The Board will notify licensees if additional extensions are approved. In the interim, licensees should take immediate action to ensure compliance with Missouri law after June 15th.
- **The Board will honor the July 31, 2020, extended pharmacy technician renewal date.** This means pharmacy technicians will still have until July 31st to renew. Technician registrations not renewed by July 31st will be deemed expired/void and the technician will not be able to work. No grace period will be given after the July 31st deadline due to the extended renewal date.

The following summary lists the waivers that will **be rescinded** and **no longer effective** after June 15th (see Attachment A for additional details):

- Unlicensed practice by non-resident pharmacists, pharmacy technicians, intern pharmacists and non-resident pharmacies during the State of Emergency
- Substitution of albuterol inhalers with inequivalent FDA-rated inhalers without prescriber approval
- Expanded emergency dispensing allowances, including, dispensing a 60-day emergency supply. **Section 338.200 would apply as enacted.*
- Waiver of designated Class-J Shared Services pharmacy permit and compliance requirements
- Compounding of commercially available products pursuant to the approved waiver
- Compounding without a patient-specific prescription
- Waiver of end-product testing for designated Risk Level 3 preparations
- Dispensing medication without a pharmacist present (even if previously verified by a pharmacist)
- Remote final product verification

- Remote pharmacy technician supervision, and
- Remote data entry by pharmacy technicians/intern pharmacists (e.g., from home). **See additional information below.**

Once again, waiver extensions requests are pending for several of the above items. Licensees will be notified if additional extensions are approved.

Licensees should take precautionary steps to protect patients and pharmacy staff as businesses begin to reopen. The Board strongly recommends using personal protective equipment when possible (gloves, face masks). Licensees should also review the CDC's guidelines for pharmacies available on the CDC's website.

IMPORTANT NOTE ON REMOTE DATA ENTRY: The Board has a pending rule that would allow remote data entry by a pharmacy technician/intern pharmacist. However, the final rule will not be effective until August 2020, due to Missouri's mandatory rulemaking requirements. The Board is discussing legal options to allow remote data entry between June 15, 2020, and the final effective date of the rule in August. Licensees will be notified of any updates. At this time, licensees should prepare to transition all pharmacy technicians/intern pharmacists performing remote data entry activities back to the pharmacy by June 15th.

ATTACHMENT A
MISSOURI BOARD OF PHARMACY
COVID-19 STATUTORY/RULE WAIVERS

(All waivers listed below will expire on **JUNE 15, 2020**. Licensees should take immediate steps to ensure compliance after June 15th. Licensees will be notified if the Board receives approval to grant additional extensions/waivers.)

STATUTE/RULE	WAIVER DESCRIPTION
§ 338.013	• Waiver granted to allow Missouri licensed pharmacies to use individuals licensed/registered as pharmacy technicians in another U.S. state or territory to provide pharmacy services during the State of Emergency, provided such non-resident license/registration is current and in good standing. *See Bd. Supplemental guidance (3/23/20) for additional guidelines. • Waiver granted to allow pharmacy technicians licensed/registered in another U.S. state or territory to practice in Missouri during the State of Emergency to assist: 1. A hospital or medical care facility that is licensed or owned by the State, and 2. A hospital or medical care facility licensed by the Missouri Department of Health and Senior Services or the Department of Mental Health.
§ 338.020	• Waiver granted to allow Missouri licensed pharmacies to use individuals licensed as pharmacists in another U.S. state or territory to provide pharmacy services during the State of Emergency, provided such non-resident license is current and in good standing. *See Bd. Supplemental guidance (3/23/20) for additional guidelines. • Waiver granted to allow pharmacists licensed in another U.S. state or territory to practice in Missouri during the State of Emergency to assist: 3. A hospital or medical care facility that is licensed or owned by the State, and 4. A hospital or medical care facility licensed by the Missouri Department of Health and Senior Services or the Department of Mental Health.

STATUTE/RULE	WAIVER DESCRIPTION
§ 338.056/20 CSR 2220-3.011(3)	Waiver granted to allow pharmacists to substitute albuterol inhalers (albuterol sulfate aerosol, metered) with other albuterol inhalers listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) with a different equivalency evaluation code during the State of Emergency if the prescribed albuterol inhaler is not available due to a shortage. This waiver applies only to "albuterol sulfate aerosol, metered" products listed in the Orange book.
§ 338.200.1(2)	Emergency Dispensing: Pharmacies may dispense an emergency supply of medication to a patient if the pharmacy that originally filled the prescription is closed or unable to fill the prescription due to the State of Emergency. Pharmacists must make a good faith effort to verify the medication to be dispensed and the authorized prescriber and dosage form (e.g., as listed on the patient's prescription vial). **This waiver applies to non-controlled substances only; § 338.200 does not apply to controlled substances.**
§ 338.200.2(1)	Emergency Dispensing: Pharmacies/pharmacists may dispense up to a sixty (60) day supply of emergency medication pursuant to § 338.220 during the State of Emergency. For unit of use medications that exceed a 30 day supply, the smallest unit of use available in inventory may be dispensed for emergency purposes. *Supply limit increased from 30 days.
§ 338.220	Waiver granted to allow Missouri licensed pharmacies to use entities licensed as a pharmacy in another U.S. State or territory to assist with providing pharmacy services during the State of Emergency, provided such non-resident license is current and in good standing. Note: A Class-J Shared Services permit is not required during the State of Emergency subject to the requirements identified in the Board's "Waiver of Statutes/Administrative Rules" statement issued on 3/18/20. See also Bd. Supplemental guidance (3/23/20) for additional guidelines.
20 CSR 2220-2.010(1)(A)	Dispensing Verified Medication: Pharmacy technicians or an intern pharmacist may dispense medication to the patient when a pharmacist is not physically present in the pharmacy due to the State of Emergency if: 1. The medication has been previously verified by a pharmacist and approved for dispensing, 2. Dispensing is necessary for patient safety or to provide disaster or emergency relief, and 3. Dispensing without the pharmacist present is approved by a pharmacist or pharmacy in advance.

STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.010(1)(B)	Remote Product Verification: To prevent illness and staffing shortages, a pharmacist may use technology to remotely verify the final product as required by 20 CSR 2220-2.010 if needed to provide disaster or emergency relief if: 1. Physical verification by a pharmacist cannot be promptly performed by a pharmacist; 2. Prompt dispensing is in the best interest of the patient's health and safety; 3. The technology used is sufficient to allow the pharmacist to properly and accurately inspect and verify the accuracy of the contents of the prescription or medication order and the affixed label, and 4. If the pharmacy technician or intern pharmacist is supervised in compliance with proposed rule 20 CSR 2220-2.710 published in the Missouri Register on March 16, 2020. In lieu of the required initial competency assessment referenced in 20 CSR 2220-2.710(2)(C), pharmacy technicians and intern pharmacists must be deemed competent to perform the duties assigned by the pharmacist-in-charge.
20 CSR 2220-2.200(10)(B)	Sterile Compounding: Pharmacies engaged in sterile compounding may accept Aseptic Technique Skill Assessment results (including media-fill testing) from another pharmacy for the same staff member, if needed to prevent interruptions in patient care or to ensure availability of pharmacy services during the State of Emergency. However, pharmacy technicians should be trained on pharmacy operational procedures to ensure proper aseptic technique.

STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.400(9)	Waiver requested to allow Missouri licensed pharmacies to compound commercially available products for hospitalized patients as authorized by and in compliance with the FDA's Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency. • Compounding is limited to the specific drugs listed in the FDA's Temporary Policy • Compounding under the FDA's Temporary Policy should only be performed by a Missouri licensed pharmacy if a hospital cannot obtain an FDA approved product or cannot obtain the compounded preparation from a properly registered/licensed drug outsourcer, and • The pharmacy notifies the Board in advance of its intent to compound pursuant to the FDA's Temporary Policy. Notifications can be e-mailed to: MissouriBOP@pr.mo.gov and should include the name, address and license number of the compounding pharmacy and the hospital(s) expected to receive the compounded preparations.

STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.400(12)	• Waiver granted to allow the distribution of compounded preparations by hospital pharmacies without a patient-specific prescription during the State of Emergency in order to: (1) treat COVID-19 patients or patients who have been relocated to other facilities due to the State or Emergency or (2) to assist other hospitals who are unable to provide the compounding services due to the State of Emergency. *For purposes of the waiver, a hospital is defined as a hospital operated by the state or a hospital licensed by the Missouri Department of Health and Senior Services or the Missouri Department of Mental Health or a Class-B pharmacy licensed by the Board. • Waiver granted 4/27/20 to also allow Missouri licensed pharmacies to compound without a patient specific prescription for hospitalized patients in compliance with the FDA's Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency, provided: 1. The pharmacy complies with FDA's Temporary Policy, including, default beyond-use dating requirements, and 2. Compounding is limited to the specific drugs listed in the FDA's Temporary Policy, and 3. The pharmacy notifies the Board in advance of its intent to compound pursuant to the FDA's Temporary Policy. Notifications can be e-mailed to: MissouriBOP@pr.mo.gov and should include the name, address and license number of the compounding pharmacy and the hospital(s) expected to receive the compounded preparations.

STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.200(14)	Waiver granted to allow Missouri licensed pharmacies compounding medication for hospitalized patients pursuant to the FDA's Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency, to release Risk Level 3 medication without end product testing results, provided: 1. The pharmacy complies with FDA's Temporary Policy, including, default beyond-use dating requirements, and 2. Testing of Risk Level 3 products cannot be completed in sufficient time to provide the requested medication in a timely manner 3. Compounding is limited to the specific drugs listed in the FDA's Temporary Policy, and 4. The pharmacy notifies the Board in advance of its intent to compound pursuant to the FDA's guidance. Notifications can be e-mailed to: MissouriBOP@pr.mo.gov and should include the name, address and license number of the compounding pharmacy and the hospital(s) expected to receive the compounded preparations.

STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.650	Class-J Shared Services: During the State of Emergency, a Missouri licensed pharmacy may provide shared pharmacy services identified in 20 CSR 2220-2.650 for another Missouri licensed pharmacy without a Class-J Shared Services permit, if the shared services are necessary to prevent interruptions in patient care as a result of pharmacy closures, limited staffing or interruptions in pharmacy operations due to COVID-19. Both pharmacies must comply with 20 CSR 2220-2.650 with the following exceptions: 1. A common database or shared real-time access to each pharmacy's electronic medication or prescription system is not required during the State of Emergency, if such database or real-time access cannot be promptly arranged in sufficient time to meet patient care needs during the State of Emergency. Pharmacists should use their professional judgment to ensure appropriate patient care and medication dispensing. 2. Pharmacies may participate in a shared services arrangement authorized by this directive without a written contract outlining authorized shared services required by 20 CSR 2220-2.650(1)(A)1. or the policy and procedure manual required by 20 CSR 2220-2.650(1)(C)1., if such contract or policy/procedure manual cannot be timely completed to meet patient needs during the emergency. However, authorized shared services should be documented in advance in writing, including, designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190 and federal law. 3. Pharmacies operating under the above allowances must comply with all provisions 20 CSR 2220-2.650 once the State of Emergency ends or upon Board termination of this authorization. A Class-J Shared Services permit and full compliance with the rule will be required at the end of the State of Emergency/Board authorization. *** The above allowances only apply to pharmacies providing shared services to a Missouri licensed pharmacy to prevent interruptions in patient care as a result of pharmacy closures, limited staffing or interruptions in pharmacy operations due to COVID-19. All other pharmacies/shared services arrangements must comply with 20 CSR 2220-2.650.

STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-6.055(6)	Non-Dispensing Activities: Pharmacists may use pharmacy technicians and intern pharmacists to assist a pharmacist with non-dispensing functions from an off-site non-pharmacy location during the State of Emergency. Pharmacists should use their professional judgment to ensure technicians/intern pharmacists are appropriately supervised.
20 CSR 2220-2.700(1) & 20 CSR 2220-6.055(6)	Remote Data Entry: Pharmacy technicians and intern pharmacists may perform remote data entry activities from home or outside of a licensed pharmacy, if the pharmacy complies with the provisions of proposed rule 20 CSR 2220-2.725 published in the Missouri Register on March 16, 2020. In lieu of the required initial competency assessment referenced in proposed 20 CSR 2220-2.725(3)(C), pharmacy technicians and intern pharmacists may perform authorized remote data entry functions if approved and deemed competent to perform the duties assigned by the pharmacist-in-charge. See also Bd. Supplemental guidance (3/23/20) for additional guidelines.

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 6— Pharmaceutical Care Standards

ORDER OF RULEMAKING

By the authority vested in the Missouri Board of Pharmacy under sections 338.140 and 338.665, RSMo, the Board adopts a rule as follows:

20 CSR 2220-6.200 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on April 15, 2020 (45 MoReg 549). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations.*

SUMMARY OF COMMENTS: The Board received four (4) comments on the proposed rule.

COMMENT: The Board received a comment from the National Association of Chain Drug Stores (NACDS) recommending the Board remove rule language in section (2) requiring that prescribing pharmacists "maintain ongoing/continued competency." NACDS stated pharmacists are medication experts and suggested the additional competency requirements are unnecessary given pharmacists are required to complete a rigorous curriculum to obtain a Pharm.D. degree. NACDS noted all accredited pharmacist curriculums require extensive training in patient care competencies.
RESPONSE: The Board recognizes the extensive and comprehensive training required for pharmacists. However, treatment guidelines and recommendations may periodically change, necessitating additional training/continuing education. The Board has determined the training requirements are appropriate to ensure patient services comply with current practice guidelines. As a result, no changes have been made in response to the comment.

COMMENT: The Board received comments from CVS Health and NACDS recommending the Board amend section (3)(A) of the rule to clearly allow an intern pharmacist or pharmacy technician to collect patient or medical history information from the patient.
RESPONSE: Chapter 338, RSMo, authorizes an intern pharmacist and pharmacy technician to assist a pharmacist in the practice of pharmacy. Pursuant to current law, intern pharmacists and pharmacy technicians may collect patient or medical histories as delegated by, and under the supervision of, a Missouri licensed pharmacist. Given the wide scope of allowed pharmacy technician/intern pharmacist activities, the Board is concerned selective identification of patient information collection in the rule may be misconstrued by licensees. The Board is currently reviewing Missouri's regulation of pharmacy technicians/intern pharmacists, including, potential promulgation of a separate rule governing authorized activities for ancillary staff. No changes have been made in response to the comments, however, the Board will consider the comments during its ongoing regulatory review. Additionally, the Board will continue to educate licensees on current allowances.

COMMENT: The Missouri Pharmacy Association (MPA) and G.L.O. & Associates (GLO) submitted comments requesting the Board amend section (3)(A) to clarify pharmacists are required to conduct patient screening based on "generally accepted" clinical guidelines to identify appropriate patients for treatment.
RESPONSE: The comments reflect the Board's intent; The rule has been modified as requested.

COMMENT: MPA and G.L.O. submitted comments requesting the Board amend section (3)(B) to clarify pharmacists may provide a prescription for a nicotine replacement therapy product to the patient, or transmit a prescription "for that patient" to a pharmacy for dispensing.
RESPONSE: The comments reflect the Board's intent; The rule has been modified as requested.

COMMENT: MPA and NACDS submitted comments requesting the Board amend section (4) to eliminate the requirement that patient medical records required by the rule must be separately maintained from other patient records. MPA expressed concerns the requirement may be costly for pharmacies or burdensome for current pharmacy software systems.
RESPONSE: The Board agrees and has modified the rule as requested.

COMMENT: NACDS submitted a comment suggesting the Board amend section (4) by deleting the list of minimum required components for documentation of patient services. NACDS indicated pharmacists would be practicing in accordance with accepted clinical guidelines and should have the discretion to use their professional judgment to determine what documentation is appropriate.
RESPONSE: The Board agrees that pharmacists should use their professional judgment when providing patient services authorized by the rule. However, section (4) would ensure proper documentation of patient services by all Board licensees. Section (4) is also similar to current statutory/rule requirements for other Missouri healthcare providers and would ensure consistency in documentation among healthcare professionals. No changes have been made in response to the comments.

COMMENT: MPA and G.L.O. submitted comments requesting the Board amend section (4)(A)2. to require pharmacists document the time a patient was seen. The commenters indicated the change may assist with third-party billing.
RESPONSE: The Board is concerned mandatory documentation of the time of a patient visit may be burdensome for pharmacies and current software systems. Additional licensee input would be appropriate prior to adopting the recommendation. The Board notes licensees may voluntarily document the patient visitation time, if desired. No changes have been made in response to this comment.

COMMENT: MPA and G.L.O. submitted comments requesting the Board amend section (4)(A)3. to require documentation of the patient's primary care provider "if determined."
RESPONSE: The suggested addition is ambiguous and may be misconstrued to require additional activities/investigation by the pharmacist. Additionally, the current proposed rule language is consistent with other Board rules that require documentation of the primary care provider (e.g., pharmacist immunization/administration). No changes have been made in

response to the comments, however, the Board will educate licensees on documentation requirements.

COMMENT: MPA and G.L.O. submitted comments requesting the Board amend section (4)(A)5. to require that pharmacists document any "additional" pertinent patient medical or medication information/history, in lieu of documenting "pertinent medical or medication information/history," as currently proposed.
RESPONSE: Section (4)(A) identifies minimum documentation requirements; Pharmacists should use their professional judgment to determine what supplementary patient medical information is needed to properly document patient care. The proposed suggestion is ambiguous and may be misconstrued. The Board notes section (4)(A) is similar to current statutory/rule requirements for other Missouri healthcare providers. The current language will ensure consistency among healthcare professionals. As a result, no changes have been made in response to the comments.

COMMENT: MPA and G.L.O. submitted comments requesting the Board amend section (2) to require that pharmacists obtain a certificate of medication therapeutic services (MTS certificate) from the Board to prescribe pursuant to § 338.665, RSMo.
RESPONSE: Pursuant to Chapter 536, the requested change constitutes a substantive amendment which cannot be adopted in a final order of rulemaking. The requested change would also require a physician protocol and additional pharmacist training that is not referenced in § 338.665, RSMo. Additional legal review and stakeholder discussion would be appropriate prior to incorporating the suggestion. No changes have been made in response to the comments, however, the Board will consider the suggestions during future rule discussions.

20 CSR 2220-6.200 Pharmacist Authority to Prescribe Pursuant to Section 338.665

(3) Pharmacist prescribing and patient care activities must be safely and properly performed.

(A) Pharmacists shall collect patient or medical history to allow the pharmacist to properly assess the patient and safely provide patient care. Prior to prescribing, the pharmacist shall use a screening procedure based on **generally accepted** clinical guidelines to identify appropriate patients for treatment. The pharmacist shall refer high-risk patients or patients with a contraindication to the patient's primary care provider or an appropriate healthcare provider, as deemed necessary or appropriate.

(B) In addition to this rule, pharmacists shall comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and record-keeping, including, but not limited to, 20 CSR 2220-2.018. Pharmacists may provide a prescription to the patient or transmit a prescription **for that patient** to a pharmacy for dispensing.

(4) Patient medical records. Prescribing pharmacists shall maintain an adequate and complete patient medical record for each patient that documents the care provided. Patient medical records must be ~~separately maintained and~~ individually retrievable.
(A) At a minimum, the required patient medical record must include:

1. The patient's name, birthdate, address and telephone number;
2. The date(s) the patient was seen;

3. The patient's primary care provider, if provided;
4. Documentation of the patient screening as required by section (3) of this rule;
5. Any pertinent medical or medication information/history;
6. The name and dosage of any medication prescribed;
7. Any recommended medication treatment plan(s) or follow-up consultation(s); and
8. Any healthcare provider referrals.

#4. COVID-19 Updates

a. Office Updates
b. Waiver Updates
c. NABP Updates
d. CDC/FDA Updates
e. COVID-19 Vaccines/COVID-19 Testing

#5. <u>2020 Legislative Implementation</u>

a. Class R Remote Dispensing Pharmacy Update
b. HB 2046/Fresh Start Act

SECOND REGULAR SESSION

[TRULY AGREED TO AND FINALLY PASSED]

CONFERENCE COMMITTEE SUBSTITUTE FOR

SENATE SUBSTITUTE FOR

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 2046

100TH GENERAL ASSEMBLY

4438H.06T 2020

AN ACT

To repeal sections 58.095, 58.451, 58.720, 190.094, 190.105, 190.143, 190.196, 193.145, 193.265, 209.334, 214.276, 256.477, 317.015, 324.009, 324.047, 324.086, 324.217, 324.262, 324.265, 324.436, 324.496, 324.523, 324.940, 324.1112, 324.1118, 326.277, 326.280, 326.289, 327.131, 327.221, 327.312, 327.381, 327.441, 327.612, 328.075, 328.150, 329.140, 331.030, 331.060, 332.231, 332.251, 332.281, 332.291, 333.041, 334.414, 334.530, 334.613, 334.616, 334.655, 334.702, 334.704, 334.706, 334.708, 334.710, 334.712, 334.715, 334.717, 334.719, 334.721, 334.725, 334.920, 336.030, 336.080, 336.110, 337.020, 337.029, 337.035, 337.050, 337.330, 337.510, 337.525, 337.615, 337.630, 337.644, 337.645, 337.665, 337.715, 337.730, 338.220, 339.040, 339.100, 339.511, 339.532, 344.030, 344.050, 345.015, 345.050, 345.065, 346.055, 346.105, and 436.230, RSMo, and section 324.009 as enacted by house committee substitute for house bill nos. 1511 & 1452, one hundredth general assembly, second regular session, and to enact in lieu thereof ninety-six new sections relating to professional registration, with existing penalty provisions.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 58.095, 58.451, 58.720, 190.094, 190.105, 190.143, 190.196,
2 193.145, 193.265, 209.334, 214.276, 256.477, 317.015, 324.009, 324.047, 324.086, 324.217,
3 324.262, 324.265, 324.436, 324.496, 324.523, 324.940, 324.1112, 324.1118, 326.277, 326.280,

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

probation on appropriate terms and conditions for a period not to exceed five years, may suspend the person's license for a period not to exceed three years, or may revoke the person's license.

3. Upon a finding that the grounds provided in subsection 2 of this section for disciplinary action are met, the office may, singly or in combination, censure or place on probation on such terms and conditions as the office deems appropriate for a period not to exceed five years, or may suspend for a period not to exceed three years or revoke the certificate, license, or permit. In any order of revocation, the office may provide that the person shall not apply for a new license for a maximum of three years and one day following the date of the order of revocation. All stay orders shall toll the disciplinary time periods allotted herein. In lieu of or in addition to any remedy specifically provided in subsection 1 of this section, the office may require of a licensee:

(1) Satisfactory completion of medical testing and/or rehabilitation programs as the office may specify; and/or

(2) A review conducted as the office may specify and satisfactory completion of medical testing and/or rehabilitation programs as the office may specify.

324.009. 1. For purposes of this section, the following terms mean:

(1) "License", a license, certificate, registration, permit, or accreditation that enables a person to legally practice an occupation or profession in a particular jurisdiction[~~; except that "license" shall not include a certificate of license to teach in public schools under section 168.021~~];

(2) "Nonresident military spouse", a nonresident spouse of an active duty member of the Armed Forces of the United States who has been transferred or is scheduled to be transferred to the state of Missouri, or who has been transferred or is scheduled to be transferred to an adjacent state and is or will be domiciled in the state of Missouri, or has moved to the state of Missouri on a permanent change-of-station basis;

(3) "Oversight body", any board, department, agency, or office of a jurisdiction that issues licenses[~~; except, for the purposes of this section, oversight body shall not include the state board of registration for the healing arts, the state board of nursing, the board of pharmacy, the state committee of psychologists, the Missouri dental board, the Missouri board for architects, professional engineers, professional land surveyors and professional landscape architects, the state board of optometry, or the Missouri veterinary medical board~~];

(4) "Resident military spouse", a spouse of an active duty member of the Armed Forces of the United States who has been transferred or is scheduled to be transferred to the state of Missouri or an adjacent state and who is a permanent resident of the state of Missouri, who is domiciled in the state of Missouri, or who has Missouri as his or her home of record.

2. Any person **[**~~who is a resident of Missouri, a resident military spouse, or a nonresident military spouse and~~**]** who holds a valid current license issued by another state, **a** territory of the United States, or the District of Columbia**, and who has been licensed for at least one year in such other jurisdiction,** may submit an application for a license in Missouri in the same occupation or profession**, and at the same practice level,** for which he or she holds the current license, along with proof of current licensure **and proof of licensure for at least one year** in **[**~~all~~**] the** other **[**~~jurisdictions~~**] jurisdiction**, to the relevant oversight body in this state.

3. The oversight body in this state shall:

(1) Within six months of receiving an application described in subsection 2 of this section **[**~~from a resident of Missouri~~**]**, waive any examination, educational, or experience requirements for licensure in this state for the applicant if it determines that **[**~~the licensing requirements in the jurisdiction that issued the applicant's license are substantially similar to or more stringent than the licensing requirements in Missouri for the same occupation or profession and shall issue such applicant a license under this section if such applicant otherwise meets the requirements of this section~~**] there were minimum education requirements and, if applicable, work experience and clinical supervision requirements in effect and the other state verifies that the person met those requirements in order to be licensed or certified in that state. An oversight body that administers an examination on laws of this state as part of its licensing application requirement may require an applicant to take and pass an examination specific to the laws of this state**; or

(2) Within thirty days of receiving an application described in subsection 2 of this section from a nonresident military spouse or a resident military spouse, waive any examination, educational, or experience requirements for licensure in this state for the applicant and issue such applicant a license under this section if such applicant otherwise meets the requirements of this section.

4. **(1)** The oversight body shall not waive any examination, educational, or experience requirements for any applicant who **has had his or her license revoked by an oversight body outside the state; who is currently under investigation, who has a complaint pending, or who** is currently under disciplinary action**, except as provided in subdivision (2) of this subsection,** with an oversight body outside the state**; who does not hold a license in good standing with an oversight body outside the state; who has a criminal record that would disqualify him or her for licensure in Missouri;** or who does not hold a valid current license in the other jurisdiction on the date the oversight body receives his or her application under this section.

(2) If another jurisdiction has taken disciplinary action against an applicant, the oversight body shall determine if the cause for the action was corrected and the matter

resolved. If the matter has not been resolved by that jurisdiction, the oversight body may deny a license until the matter is resolved.

5. **[**~~The oversight body shall not waive any examination, educational, or experience requirements for any applicant if it determines that waiving the requirements for the applicant may endanger the public health, safety, or welfare.~~

~~6.~~**]** Nothing in this section shall prohibit the oversight body from denying a license to an applicant under this section for any reason described in any section associated with the occupation or profession for which the applicant seeks a license.

6. Any person who is licensed under the provisions of this section shall be subject to the applicable oversight body's jurisdiction and all rules and regulations pertaining to the practice of the licensed occupation or profession in this state.

7. This section shall not be construed to waive any requirement for an applicant to pay any fees, post any bonds or surety bonds, or submit proof of insurance associated with the license the applicant seeks.

8. This section shall not apply to business, professional, or occupational licenses issued or required by political subdivisions.

9. **The provisions of this section shall not impede an oversight body's authority to require an applicant to submit fingerprints as part of the application process.**

10. The provisions of this section shall not apply to an oversight body that has entered into a licensing compact with another state for the regulation of practice under the oversight body's jurisdiction. The provisions of this section shall not be construed to alter the authority granted by, or any requirements promulgated pursuant to, any interjurisdictional or interstate compacts adopted by Missouri statute or any reciprocity agreements with other states**[**~~.~~ ~~If any conflict arises between the provisions of this section and the provisions of any interjurisdictional or interstate compact or reciprocity agreement, the provisions of such compact or agreement shall prevail. If a conflict arises between the provisions of this section and any federal law or rule, the provisions of the federal law or rule shall prevail~~**] in effect on August 28, 2018, and whenever possible this section shall be interpreted so as to imply no conflict between it and any compact, or any reciprocity agreements with other states in effect on August 28, 2018**.

[~~10. For the purposes of this section, resident military spouses and nonresident military spouses shall be eligible to apply for a license with any board, department, agency, or office of a jurisdiction that issues licenses including, but not limited to, the state board of registration for the healing arts; the state board of nursing; the board of pharmacy; the state committee of psychologists; the Missouri dental board; the Missouri board for architects, professional~~

~~engineers, professional land surveyors, and professional landscape architects; the state board of optometry; and the Missouri veterinary medical board.~~]

11. Notwithstanding any other provision of law, a license issued under this section shall be valid only in this state and shall not make a licensee eligible to be part of an interstate compact. An applicant who is licensed in another state pursuant to an interstate compact shall not be eligible for licensure by an oversight body under the provisions of this section.

12. The provisions of this section shall not apply to any occupation set forth in subsection 6 of section 290.257, or any electrical contractor licensed under sections 324.900 to 324.945.

324.012. 1. This section shall be known and may be cited as the "Fresh Start Act of 2020".

2. As used in this section, the following terms mean:

(1) "Criminal conviction", any conviction, finding of guilt, plea of guilty, or plea of nolo contendere;

(2) "Licensing", any required training, education, or fee to work in a specific occupation, profession, or activity in the state;

(3) "Licensing authority", an agency, examining board, credentialing board, or other office of the state with the authority to impose occupational fees or licensing requirements on any profession. The term "licensing authority" shall not include the state board of education's licensure of teachers pursuant to chapter 168, the Missouri state board of accountant's licensure of accountants pursuant to chapter 326, the board of podiatric medicine's licensure of podiatrists pursuant to chapter 330, the Missouri dental board's licensure of dentists pursuant to chapter 332, the state board of registration for the healing art's licensure of physicians and surgeons pursuant to chapter 334, the Missouri state board of nursing's licensure of nurses pursuant to chapter 335, the board of pharmacy's licensure of pharmacists pursuant to chapter 338, the Missouri real estate commission's licensure of real estate brokers, real estate salespersons, or real estate broker-salespersons pursuant to sections 339.010 to 339.205, the Missouri veterinary medical board's licensure of veterinarian's pursuant to chapter 340, the Missouri director of finance appointed pursuant to chapter 361, or the peace officer standards and training commission's licensure of peace officers or other law enforcement personnel pursuant to chapter 590;

(4) "Political subdivision", a city, town, village, municipality, or county.

3. Notwithstanding any other provision of law, beginning January 1, 2021, no person shall be disqualified by a state licensing authority from pursuing, practicing, or

engaging in any occupation for which a license is required solely or in part because of a prior conviction of a crime in this state or another state, unless the criminal conviction directly relates to the duties and responsibilities for the licensed occupation as set forth in this section or is violent or sexual in nature.

4. Beginning August 28, 2020, applicants for examination of licensure who have pleaded guilty to, entered a plea of nolo contendere to, or been found guilty of any of the following offenses or offenses of a similar nature established under the laws of this state, any other state, United States, or any other country, notwithstanding whether sentence is imposed, shall be considered by state licensing authorities to have committed a criminal offense that directly relates to the duties and responsibilities of a licensed profession:

(1) Any murder in the first degree, or dangerous felony as defined under section 556.061 excluding an "intoxication-related traffic offense" or "intoxication-related boating offense" if the person is found to be a "habitual offender" or "habitual boating offender" as such terms are defined in section 577.001;

(2) Any of the following sexual offenses: rape in the first degree, forcible rape, rape, statutory rape in the first degree, statutory rape in the second degree, rape in the second degree, sexual assault, sodomy in the first degree, forcible sodomy, statutory sodomy in the first degree, statutory sodomy in the second degree, child molestation in the first degree, child molestation in the second degree, sodomy in the second degree, deviate sexual assault, sexual misconduct involving a child, sexual misconduct in the first degree under section 566.090 as it existed prior to August 28, 2013, sexual abuse under section 566.100 as it existed prior to August 28, 2013, sexual abuse in the first or second degree, enticement of a child, or attempting to entice a child;

(3) Any of the following offenses against the family and related offenses: incest, abandonment of a child in the first degree, abandonment of a child in the second degree, endangering the welfare of a child in the first degree, abuse of a child, using a child in a sexual performance, promoting sexual performance by a child, or trafficking in children; and

(4) Any of the following offenses involving child pornography and related offenses: promoting obscenity in the first degree, promoting obscenity in the second degree when the penalty is enhanced to a class E felony, promoting child pornography in the first degree, promoting child pornography in the second degree, possession of child pornography in the first degree, possession of child pornography in the second degree, furnishing child pornography to a minor, furnishing pornographic materials to minors, or coercing acceptance of obscene material;

(5) The offense of delivery of a controlled substance, as provided in section 579.020, may be a disqualifying criminal offense for the following occupations: real estate appraisers and appraisal management companies, licensed pursuant to sections 339.500 to 339.549; and nursing home administrators, licensed pursuant to chapter 344; and

(6) Any offense an essential element of which is fraud may be a disqualifying criminal offense for the following occupations: private investigators, licensed pursuant to sections 324.1100 to 324.1148; accountants, licensed pursuant to chapter 326; architects, licensed pursuant to sections 327.091 to 327.172; engineers, licensed pursuant to sections 327.181 to 327.271; land surveyors, licensed pursuant to sections 327.272 to 327.371; landscape architects, licensed pursuant to sections 327.600 to 327.635; chiropractors, licensed pursuant to chapter 331; embalmers and funeral directors, licensed pursuant to chapter 333; real estate appraisers and appraisal management companies, licensed pursuant to sections 339.500 to 339.549; and nursing home administrators, licensed pursuant to chapter 344.

5. If an individual is charged with any of the crimes set forth in subsection 4 of this section, and is convicted, pleads guilty to, or is found guilty of a lesser included offense and is sentenced to a period of incarceration, such conviction shall only be considered by state licensing authorities as a criminal offense that directly relates to the duties and responsibilities of a licensed profession for four years, beginning on the date such individual is released from incarceration.

6. (1) Licensing authorities shall only list criminal convictions that are directly related to the duties and responsibilities for the licensed occupation.

(2) The licensing authority shall determine whether an applicant with a criminal conviction listed under subdivision (1) of this subsection will be denied a license based on the following factors:

(a) The nature and seriousness of the crime for which the individual was convicted;

(b) The passage of time since the commission of the crime, including consideration of the factors listed under subdivision (3) of this subsection;

(c) The relationship of the crime to the ability, capacity, and fitness required to perform the duties and discharge the responsibilities of the occupation; and

(d) Any evidence of rehabilitation or treatment undertaken by the individual that might mitigate against a direct relation.

(3) If an individual has a valid criminal conviction for a criminal offense that could disqualify the individual from receiving a license, the disqualification shall not apply to an

individual who has been exonerated for a crime for which he or she has previously been convicted of or incarcerated.

7. An individual with a criminal record may petition a licensing authority at any time for a determination of whether the individual's criminal record will disqualify the individual from obtaining a license. This petition shall include details on the individual's criminal record. The licensing authority shall inform the individual of his or her standing within thirty days after the licensing authority has met, but in no event more than four months after receiving the petition from the applicant. The decision shall be binding, unless the individual has subsequent criminal convictions or failed to disclose information in his or her petition. The licensing authority may charge a fee by rule to recoup its costs as set by rule making authority not to exceed twenty-five dollars for each petition.

8. (1) If a licensing authority denies an individual a license solely or in part because of the individual's prior conviction of a crime, the licensing authority shall notify the individual in writing of the following:

(a) The grounds and reasons for the denial or disqualification;

(b) That the individual has the right to a hearing as provided by chapter 621 to challenge the licensing authority's decision;

(c) The earliest date the person may reapply for a license; and

(d) That evidence of rehabilitation may be considered upon reapplication.

(2) Any written determination by the licensing authority that an applicant's criminal conviction is a specifically listed disqualifying conviction and is directly related to the duties and responsibilities for the licensed occupation shall be documented with written findings for each of the grounds or reasons under paragraph (a) of subdivision (1) of this subsection by clear and convincing evidence sufficient for a reviewing court.

(3) In any administrative hearing or civil litigation authorized under this subsection, the licensing authority shall carry the burden of proof on the question of whether the applicant's criminal conviction directly relates to the occupation for which the license is sought.

9. The provisions of this section shall apply to any profession for which an occupational license is issued in this state, including any new occupational license created by a state licensing authority after August 28, 2020. Notwithstanding any other provision of law, political subdivisions shall be prohibited from creating any new occupational licenses after August 28, 2020. The provisions of this section shall not apply to business licenses, where the terms "occupational licenses" and "business licenses" are used interchangeably in a city or county charter definition.

324.025. 1. The provisions of this section shall be known and may be cited as the "Expanded Workforce Access Act of 2020".

2. For purposes of this section, the following terms mean:

(1) "Apprenticeship", a program that the United States Department of Labor deems to meet the federal guidelines set out in 29 CFR Part 29 and 29 U.S.C. Section 50;

(2) "License", a license, certificate, registration, permit, or accreditation that enables a person to legally practice an occupation, profession, or activity in the state;

(3) "Licensing authority", an agency, examining board, credentialing board, or other office of the state with the authority to impose occupational fees or licensing requirements on any profession.

3. Beginning January 1, 2021, within the parameters established under the federal Labor Standards For the Registration of Apprenticeship Programs under 29 CFR Part 29 and 29 U.S.C. Section 50, each state licensing authority shall grant a license to any applicant who meets the following criteria:

(1) Successfully completed the eighth grade;

(2) Completed an apprenticeship approved by the division of professional registration or the United States Department of Labor, or otherwise permitted under state or federal law; and

(3) Passed an examination, if one is deemed to be necessary, by the appropriate licensing authority.

4. (1) The appropriate licensing authority shall establish a passing score for any necessary examinations under the apprenticeship program which shall not exceed any passing scores that are otherwise required for a non-apprenticeship license for the specific profession.

(2) If there is no examination requirement for a non-apprenticeship license, no examination shall be required for applicants who complete an apprenticeship.

(3) The number of working hours required for a competency-based apprenticeship or a hybrid apprenticeship under 29 CFR 29.5 shall not exceed the number of educational hours otherwise required for a non-apprenticeship license for the specific profession.

5. Any department with oversight over a licensing authority may promulgate all necessary rules and regulations for the implementation 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, 2020, shall be invalid and void.

6. The provisions of this section shall not apply to any occupation set forth in section 290.257, or any electrical contractor licensed under sections 324.900 to 324.945.

324.035. 1. No board, commission, or committee within the division of professional registration shall utilize occupational fees, or any other fees associated with licensing requirements, or contract or partner with any outside vendor or agency for the purpose of offering continuing education classes.

2. Nothing in this section shall be construed to preclude a board, commission, or committee within the division of professional registration from utilizing occupational licensure fees for the purpose of participating in conferences, seminars, or other outreach for the purpose of communicating information to licensees with respect to changes in policy, law, or regulations.

324.047. 1. The purpose of this section is to promote general welfare by establishing guidelines for the regulation of occupations and professions not regulated prior to January 1, 2019, and guidelines for combining any additional occupations or professions under a single license regulated by the state prior to January 1, 2019.

2. For purposes of this section, the following terms mean:

(1) "Applicant group", any occupational or professional group or organization, any individual, or any other interested party that seeks to be licensed or further regulated or supports any bill that proposes to combine any additional occupations or professions under a single license regulated by the state prior to January 1, 2019;

(2) "Certification", a program in which the government grants nontransferable recognition to an individual who meets personal qualifications established by a regulatory entity. Upon approval, the individual may use "certified" as a designated title. This term shall not be synonymous with an occupational license;

(3) "Department", the department of commerce and insurance;

(4) "Director", the director of the division of professional registration;

(5) "Division", the division of professional registration;

(6) "General welfare", the concern of the government for the health, peace, morality, and safety of its residents;

(7) "Lawful occupation", a course of conduct, pursuit, or profession that includes the sale of goods or services that are not themselves illegal to sell irrespective of whether the individual selling them is subject to an occupational regulation;

#6. <u>FDA Compounding MOU</u>

c. FDA Updates
d. Rule Discussion Draft

COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 2- General Rules

***** DRAFT*** PROPOSED RULE**

20 CSR 2220-2.425. Required Pharmacy Reporting.

Purpose: *The purpose of this rule is to establish requirements for reporting compounding information to the Missouri Board of Pharmacy to ensure compliance with state and federal law.*

(1) Pharmacies which have distributed or dispensed compounded human drug products pursuant to prescriptions or medication orders in the previous calendar year, shall annually report the following information on a form provided by the Board:

(A) The number of prescriptions or medication orders for compounded human drug products that the pharmacy distributed or dispensed interstate during the previous calendar year;

(B) The number of prescriptions or medication orders for compounded human drug products that the pharmacy sent out (or caused to be sent out) from the facility in which the drug products were compounded during the previous calendar year;

(C) The number of prescription or medication orders for compounded human drug products dispensed on-site at the pharmacy during the previous calendar year (e.g., picked up the patient or the patient's designee).

(D) The sum of the figures from sub-sections (1)(B) and (1)(C) above.

(E) The quotient from dividing the figure in sub-section (1)(A) by the figure from sub-section (1)(D)

(2) If the figure in subsection (1)(E) is greater than 0.5, the pharmacy shall also report the following information:

(A) The total number of prescription or medication orders for sterile compounded human drugs distributed or dispensed interstate during the previous calendar year;

(B) A list of the States where the pharmacy was licensed during the previous calendar year.

(C) A list of the States into which the pharmacy distributed compounded human drug products during the previous calendar year.

(3) The required information shall be reported no later than January 31, each calendar year.

(4) Notwithstanding the above, a pharmacy which participates in and reports all information required by this rule to the National Association of Boards of Pharmacy (NABP) Information Sharing Network shall not be required to also report to the Board. Pharmacies reporting to NABP's Sharing Network shall notify the Board no later than January 31, each calendar year that information required by this rule has been reported to NABP. A copy of information submitted to NABP pursuant to this rule shall be provided to the Board or the Board's authorized designee within five (5) business days of a request from the Board/Board designee.

#7. UMKC School of Pharmacy/STLCoP Annual School Meeting

a. UMKC School Update
b. STLCOP School Update
c. Board discussion/Q&A
d. Review of special site/non-pharmacist preceptor lists.

20 CSR 2220-2.120 Transfer of Prescription or Medication Order Information

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

(1) A valid new or refill prescription or medication order may be transferred to another pharmacy if—

(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 applicable state and federal controlled substance laws and regulations; and

(E) The transfer of information for a controlled substance 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) The following record-keeping is required when a prescription, medication order, or refill is transferred:

(A) The prescription record at the transferring pharmacy must show—

1. The word void must appear on the face of the invalidated prescription for pharmacies using a manual record-keeping system. For pharmacies using an electronic data processing system, the prescription or medication order must be promptly voided within the system;

2. The name and location of the pharmacy to which it was transferred, the date of transfer, and the identity of the persons transferring and receiving information; and

3. If the transfer involves a controlled substance, the receiving pharmacy's address and Drug Enforcement Administration (DEA) registration number and the full name of the pharmacist(s) transferring and receiving the prescription information; and

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

1. An indication that the prescription or medication order is a transfer;

2. Date of issuance;

3. Date of first dispensing;

4. Number of refills originally authorized and the number of remaining refills;

5. Date of last refill;

6. Prescription number or other unique identifier;

7. The name and location of the pharmacy that transferred the prescription or medication order;

8. The identity of the individuals transferring and receiving the information;

9. If the transfer involves a controlled substance, the transferring pharmacy's address and DEA registration number and the full names of the pharmacists transferring and receiving the prescription or medication order information; and

10. If the transfer involves information for a prescription or medication order that has never been dispensed, the date of first dispensing, the date of last refill, and the prescription number/unique identifier are not required.

(3) An electronic transfer of prescription or medication order between licensed pharmacies must meet all of the requirements of this rule. However, licensed 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.

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

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

Pure standards of practice approach:

(5) Pharmacies receiving a request to transfer a prescription/medication order must complete the transfer in a timely manner.

Hybrid standards of practice approach:

(5) A pharmacy receiving a request to transfer a prescription or medication order from the patient or the patient's designee must complete the transfer in a timely manner but no later than one (1) business day of receiving the request. If [reasonable] cause exists to question the validity of a transfer request received from another pharmacy or from a source other than the patient or the patient's designee, a pharmacist may use their professional judgment [and take additional steps] to verify the transfer request is valid, provided the transfer must be completed within two (2) business days.

*****COMPLETE STANDARDS OF PRACTICE REVISION***:**

20 CSR 2220-2.120 Transfer of Prescription or Medication Order Information

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

(1) ~~A valid new or refill prescription or medication order may be transferred to another pharmacy if—~~

~~(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 applicable state and federal controlled substance laws and regulations; and~~

~~(E) The transfer of information for a controlled substance 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.~~

(1) A valid new or refill prescription or medication order may be transferred to another pharmacy if the prescription or medication order and/or refills have not exceeded the maximum allowable time limit or lawfully allowable refills. Controlled substance transfers must comply with state and federal law.

(2) ~~The following record-keeping is required when a prescription, medication order, or refill is transferred.~~ Prescription or medication order transfers must be adequately documented in the pharmacy's records.

(A) The prescription record at the transferring pharmacy must show—

1. ~~The word void must appear on the face of the invalidated prescription for pharmacies using a manual record-keeping system. For pharmacies using an electronic data processing system, the prescription or medication order must be promptly voided within the system;~~ Transferred prescriptions/medication orders must be voided or otherwise deactivated in the transferring pharmacy's records to prevent further dispensing;

2. The name and ~~location~~ address of the pharmacy to which it was transferred, the date of transfer, ~~and the identity of the persons transferring and receiving information~~; and

3. ~~If the transfer involves a controlled substance, the receiving pharmacy's address and Drug Enforcement Administration (DEA) registration number and the full name of the pharmacist(s) transferring and receiving the prescription information; and~~ Any other information required by state or federal controlled substance laws.

(B) ~~The record at the receiving pharmacy shall show all of the following, in addition to all other lawfully required information~~ The receiving pharmacy must maintain the following records:

1. An indication that the prescription or medication order is a transfer;

~~2. Date of issuance;~~

~~3. Date of first dispensing;~~

4. Number of refills originally authorized and the number of remaining refills;

5. Date of last refill;

~~6. Prescription number or other unique identifier;~~

7. The name and ~~location~~ address of the pharmacy that transferred the prescription or medication order;

8. The identity of the individuals transferring and receiving the information;

9. ~~If the transfer involves a controlled substance, the transferring pharmacy's address and DEA registration number and the full names of the pharmacists transferring and receiving the prescription or medication order information~~ Any other information required by state and federal controlled substance laws; and

~~10. If the transfer involves information for a prescription or medication order that has never been dispensed, the date of first dispensing, the date of last refill, and the prescription number/unique identifier are not required.~~

(3) An electronic transfer of prescription or medication order between licensed pharmacies must meet all of the requirements of this rule. However, licensed 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.

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

(5) ~~A pharmacy receiving a transfer request from a patient or another pharmacy must complete the transfer within one (1) business day of receiving the request.~~ Pharmacies receiving a request to transfer a prescription/medication order must complete the transfer in a timely manner.

IDAHO RULE: *405. FILLING PRESCRIPTION DRUG ORDERS: TRANSFERS. A prescription drug order may be transferred within the limits of federal law. Drug outlets using a common electronic file are exempt from transfer limits.*

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019.

#8 <u>20 CSR 2220-2.120 Transfer of Prescription or Medication Order Information</u>

a. Discussion draft amendment

#9. General Office Updates

a. Office Updates
b. Licensing Updates
c. Rule Update/Future Rule Review Planning
d. 2021 Legislative Updates
e. Budget Updates
f. Rx Cares for Missouri Medication Disposal

#10. Future Meeting Dates/Topics

a. Proposed Meeting Dates/Times

2021

January

S	M	T	W	T	F	S
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February

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March

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April

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May

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June

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July

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August

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September

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October

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31						

November

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December

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Holidays

1/1/2021	7/5/2021
1/18/2021	9/6/2021
2/12/2021	10/11/2021
2/15/2021	11/11/2021
5/7/2021	11/25/2021
5/31/2021	12/24/2021

Board Meetings

Proposed Dates

1/13-1/14
2/17
3/24
4/14-4/15

Conference Calls

National Meetings

2/7-9/2021 (NACDS Regional)
TO BE DETERMINED (MPA Annual)
3/12-15/2021 (APhA)
4/7/2021 MPA Legislative Day
3/18-20/2021 (MSHP)
4/24-27/2021 (NACDS Annual)