Notice is hereby given that the Missouri Hospital Advisory Committee will be meeting at 10:00 a.m. on March 1, 2019. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 10:00 a.m. on March 1, 2019.

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, 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.
TENTATIVE AGENDA
Missouri Board of Pharmacy
Hospital Advisory Committee

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

March 1, 2019
10:00 a.m

OPEN SESSION AGENDA

1. Call to Order/Roll Call: Chairman Teale

2. Welcome & Introductions

3. New Member Orientation
   a. Committee Member Introductions
   b. Role of the Committee Overview
   c. Sunshine Law Overview
   d. Committee Vacancies/MPA appointee

4. Approval of Minutes
   a. October 18, 2018
   b. January 19, 2019

5. Board of Pharmacy Update
   a. 2019 Legislation
   b. Chapter 338 Review
   c. Bd. meeting updates

6. Missouri DHSS Update
   a. Pending DHSS Rules
   b. Other Updates

7. Missouri Hospital Association Update
   a. Pharmacy Technician Proposed Legislation
   b. Pharmacist Scope of Practice
   c. SB 357 & Hospital Applicability

8. Missouri Society of Health System Pharmacists Update

9. Missouri Pharmacy Association Update

a. SB 357 (RPh Scope of Practice)
b. SB 127 (Importation Study)
c. SB 274 (Pharmacy Pilot Projects)
d. SB 309 (Tobacco Cessation)
e. SB 155 (PDMP)
f. HB 257 (Bd. Disc. Agreements)
g. HB 293 (E-Prescribing)
h. HB 487 (Contraceptives)
i. HB 667 (Foreign Distributors)
j. HB 727 (Dispensing on Hospital Discharge)

11. Disposal of Patient Home Medications by a Hospital
   a. Draft BNDD/DHSS Guidance Statement
   b. MHA and MSHP Guidance

12. Non-Sterile Packaging in Clinics

13. Pharmacist Administration in Hospital/Acute Care Settings

14. Future Meeting Dates/Topics

15. Adjournment
4. Approval of Minutes
   a. October 18, 2018
   b. January 19, 2019
The Missouri Hospital Advisory Committee met in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed.

**Committee Members Present**
Greg Teale, R.Ph., Chairman  
James Gray, R.Ph., Member  
Colby Grove, R.Ph., Member  
Nathan Hanson, R.Ph., Member  
David Wolfrath, R.Ph., Member

**Committee Members Absent**
Daniel Good, R.Ph., Chairman

**Board Members/Staff Present**
Barbara Bilek, Board Member  
Kimberly Grinston, Executive Director  
Katie DeBold, Inspector

**Others Present**
Ron Fitzwater, Missouri Pharmacy Association  
William Koebel, DHSS  
Sarah Willson, Missouri Hospital Association  
John Rossen (Mosaic Healthcare)

Chairman Teale opened the meeting at approximately 10:03 a.m. and roll-call was taken. Mr. Teale reported Daniel Good would not be attending and welcomed Nathan Hanson to the Committee.

**Agenda Item # 2 (Approval of Minutes):**
- February 1, 2018
- March 20, 2018
A motion was made by James Gray, seconded by David Wolfrath, to approve the minutes for February 1, 2018, and March 20, 2018. The motion passed 4:0:0:1 with roll call vote as follows:

James Gray – Yes        Colby Grove- Yes        Daniel Good – Absent
Nathan Hanson – Yes     David Wolfrath- Yes

**Agenda Item # 3 (Board of Pharmacy Updates):** Kimberly Grinston reported the Board will be meeting on October 24th-25th and will be considering participation in the Missouri Workforce Development database operated by the University of Missouri. The database would collect statistical licensing data that may assist in analyzing Missouri’s pharmacy workforce and identifying underserved pharmacy areas. Committee members suggested the data may also help support expanded scope of practice or pharmacist provider status.

**Agenda Item # 4 (DHSS Updates):** Kimberly Grinston stated DHSS representatives were unable to attend due to illness and previously scheduled meetings. Sarah Willson reported DHSS recently informed MHA the proposed hospital pharmacy rules may be delayed because of a change in DHSS general counsel. Mrs. Willson indicated MHA expressed its strong support for moving the rules forward and offered to provide assistance if needed. Chairman Teale asked if hospitals are subject to CMS standards or the prior DHSS rules. Mrs. Willson indicated state rules are technically preempted and noted DHSS surveyors are currently surveying to CMS standards and not citing state violations.

**Agenda Item # 5 (Missouri Hospital Association Updates):** Sarah Willson provided the following updates:

- Another Missouri hospital recently closed; Other critical access hospitals may be at risk.
- MHA has been monitoring issues related to reduction of the outpatient reimbursement rate if a contract isn’t in place with a managed care organization (MCO). Mrs. Willson indicated Missouri law currently provides a MCO can reimburse at 90% of the Medicaid rate if there isn’t an MCO contract. Mr. Teale suggested this appears to give MCOs an incentive not to contract. Mrs. Willson reported the concept had equal support and resistance during a recent Joint Commission on Administrative rules hearing and suggested a legislative change may be the best solution.
- CMS recently updated its upper payment limit. Missouri is strictly interpreting the new limit while other states have taken a different approach. Mrs. Willson suggested Medicaid reductions could be well above $100 million. MHA is actively working with MoHealthNet and CMS to determine what is reasonable and what the correct interpretation should be. MHA’s goal is to mitigate losses as much as possible.
- MHA will be meeting with the Missouri Pharmacy Association to discuss legislation that would expand pharmacist scope of practice and pharmacy technician activities.
• MHA will be sponsoring a webinar on October 29th regarding 2018 legislation; The Board of Pharmacy and MSHP will be presenting.
• National hospital representatives will be meeting with CMS to discuss common survey/certification issues and other healthcare concerns. Committee members were asked to forward any suggestions to Mrs. Willson’s attention.

Greg Teale asked MHA for updates on a meeting recently held with hospitals/healthcare practitioners and MoHealthNet to discuss reimbursement concerns. Mrs. Willson stated she will consult with Brian Kinkade who may be more familiar with developments. Mr. Teale advised the FDA is hosting an open session on NDC changes which may significantly impact healthcare systems.

Further Committee discussion held on high school programs offered by hospitals to attract young adults to the healthcare profession. James Gray indicated Barnes-Jewish has a high school program, however, students may not be able to find employment in some of the healthcare deserts after they are trained. Mrs. Willson stated an adequate healthcare community is crucial for business development and suggested corporations may not relocate to Missouri if there isn’t a strong healthcare community/workforce.

Agenda Item # 6 (2018/2019 Proposed Legislation): The Committee reviewed the legislation included in the agenda. The following discussion was held:
• HB 1870: Kimberly Grinston reported the bill was not enacted; Sarah Willson noted similar multi-dose dispensing language is included in the proposed DHSS rules.
• HB 2183: Sarah Willson reported the bill passed; MHA held a webinar and sent educational materials to hospitals on how to add additional locations to their hospital license. Barbara Bilek asked if a DHSS inspection would be required; Mrs. Willson stated it would depend on how the change is submitted.
• Pharmacist Scope of Practice: Greg Teale reported MSHP, MPA and MHA met to discuss potential legislation that would expand pharmacist scope of practice by allowing pharmacists to prescribe both controlled and non-controlled substances and allow expanded pharmacy technician duties such as tech-check-tech. Mrs. Willson indicated MHA subsequently met with BNDD to discuss legal issues; BNDD advised Chapter 338 may need to be amended to grant the Board authority to issue some form of certificate of controlled substance authority. Nathan Hanson noted the state of Washington included reimbursement provisions in similar legislation and recommended the Board or MHA review VA’s reimbursement programs/models.

Committee discussion held on pharmacist prescribing authority; Mrs. Grinston indicated the Board is not opposed to pharmacist prescribing but had concerns with the technician expansion language, especially tech-check-tech. Mrs. Willson stated some hospitals have less than a 1% financial margin and are trying to identify viable options to affordably provide services.
Agenda Item # 3 (Board of Pharmacy Updates- Cont’d)- Committee members reviewed the proposed Class-B section of the Missouri Pharmacy Practice Guide. Suggested changes are incorporated in Attachment 1.

Agenda Item # 8 (2019 Priorities/Discussion Items):

- Guideline on Non-Class B Hospital Pharmacy Activities: Greg Teale suggested tabling this issue until after DHSS’ hospital pharmacy rules are finalized. Committee members asked if a hospital clinic needed a drug distributor license to distribute medication to a Class-B pharmacy; Kimberly Grinston reported a drug distributor license would be required but noted a Class-B pharmacy could accept returns of medication distributed by the Class-B pharmacy to the clinic. Committee members asked to include guidance on this issue in the Missouri Pharmacy Practice Guide.
- Non-Sterile Packaging for Clinics: Greg Teale asked about labeling requirements if a hospital pharmacy repackages large amounts of medication for distribution throughout the healthcare system; Committee consensus to research further and consult with the Board’s Chief Inspector.
- USP Chapter 800: Greg Teale stated the new Chapter may significantly impact hospitals; Katie DeBold reported DHSS recently suggested they would be enforcing the new standards but didn’t take a firm position. James Gray and Greg Teale indicated compliance costs could exceed $10 million per hospital based on operations. Committee consensus to discuss potential avenues for addressing Chapter 800 enforcement concerns.
- Opioid Management: Committee members expressed concerns with the increase in heroin use and discussed potential pharmacy solutions, including, mandatory e-prescribing, enhanced medication assisted therapy, drug take-back and enhanced pharmacist/prescriber consulting opportunities. Ron Fitzwater indicated MPA may support mandatory e-prescribing for controlled substances. Committee consensus to maintain as a future discussion topic.
- After-Hours Dispensing: Committee members indicated questions still exist regarding rule requirements, however, this topic is a lower priority item.
- Pharmacy Technician Roles & Responsibilities: James Gray noted the pending DHSS rules may impact this issue. Committee members asked if the Board’s previous technician training/education proposal was included in the Board’s 2019 legislative package; Kimberly Grinston stated the proposal was re-submitted with minor changes.

Committee discussion held on future agenda items/prioritization of discussion topics. Discussion topics were ranked as follows:

1. Non-Sterile Packaging for Clinics (Ranked # 1 because the item could be resolved quickly although not a top priority)
2. Medication Take-Back
3. Multi-Dose Dispensing from Hospitals
4. Opioid Management
5. Medical Marijuana/Potential Impact on Healthcare Systems
6. USP Chapter 800

Additional research was requested on the following items:
   1. Central repackaging
   2. Requirements for pharmacist administration within a DHSS facility
   3. Medication returns from a hospital clinic to a Class-B hospital pharmacy. Kimberly Grinston stated language on this will be added to the Pharmacy Practice Guide

The following items were removed from the active discussion list at this time:
   1. After-Hours Dispensing to employees/patients, on discharge and from the Emergency Department
   2. Guidance on Non-Class B Hospital Pharmacy Activities (held pending finalization of DHSS' rules)

**Agenda Item # 9 (Future Meeting Dates)**- Committee Consensus to meet on January 18, 2019 at 9:30 a.m.

At 2:20 p.m., a motion was made by James Gray, seconded by David Wolfrath, to adjourn the October 18, 2018 meeting. The motion passed 4:0:0:1 with roll call vote as follows:

- James Gray – Yes
- Colby Grove- Yes
- Nathan Hanson – Yes
- David Wolfrath- Yes
- Daniel Good – Absent

THE MEETING WAS ADJOURNED.

______________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
D.7 CHANGE OF LOCATION/REMODELING

Pharmacy permits are only valid for the address identified on the permit. A Pharmacy Location Change application must be filed with the Board before the pharmacy moves to a new location (an inspection is required for in-state pharmacies). [20 CSR 2220-2.020(4)]. If approved, the Board will issue a permit for the new location with the previous permit number. Licensees may not begin operating at the new location until a new license is issued. Note: Permit holders should notify the Board in writing if the pharmacy’s address changes but not the location. An amended permit will be issued without charge.

Remodeling: A Pharmacy Location Change application is not required for remodeling within an existing structure. However, permit holders must file an affidavit that includes a description of the proposed changes and the projected completion date. [20 CSR 2220-2.020(4)(A)]. The remodeling affidavit and project plans must be filed with the Board no later than thirty (30) days before the changes begin. Rule 20 CSR 2220-2.020(4)(A) defines remodeling as: 1) any change in the storage conditions of Schedule II substances, 2) any new connections to water/sewer resources, or 3) any changes in the overall physical security of drugs stored in the pharmacy.

A move to a temporary structure outside of the existing building during a facility renovation is considered a change of location. A move back to the renovated area is considered a second location change. Both moves require a separate Location Change application (and an inspection for resident pharmacies).

Licensees should check with BNDD and the DEA to determine if a new or amended controlled substance registration is also required.

D.8 TERMINATING BUSINESS

Prior to terminating business, the PIC and the permit holder should ensure proper arrangements have been made for all inventory and pharmacy records. An Out-of-Business Notification Form must be filed with the Board within fifteen (15) days after the permit holder stops operating. [20 CSR 2220-2.015(1)]. The pharmacy’s permit must also be returned to the Board office.

The closing pharmacy may transfer or dispose of medication in accordance with state and federal law. [20 CSR 2220-2.015(2)]. A drug distributor license is not required for a one-time transfer of medication/devices if the pharmacy is terminating business. [20 CSR 2220-2.015(3)]. Pharmacies may not transfer misbranded, outdated or adulterated drugs, except for proper disposal.

A complete inventory of all controlled substances transferred or disposed of must be completed on the termination date. [20 CSR 2220-2.015(2)(A)]. A copy of the inventory must be included in the records of each permit holder involved in the transfer. Controlled substances must be transferred via invoice or, if applicable, a DEA-222 form/CSOS.

Records: The closing pharmacy must designate a secure location where pharmacy records will be kept after the pharmacy is closed. The Board recommends informing patients of where/how to locate prescription records in the future. Records transferred to an unlicensed location must be retrievable within seven (7) working days of a Board request. [20 CSR 2220-2.015(1)(C)]

D.9 CLASS-B HOSPITAL PHARMACY

A Class B Hospital Pharmacy is defined as:

- A pharmacy owned, managed, or operated by a hospital as defined by § 197.020, or
- A “hospital clinic or facility” that is under common control, management or ownership of the same hospital or hospital system. [§ 338.165.1(3)].

A Class B pharmacy can provide pharmacy services to the general public, including, to hospital staff and hospital outpatients. A separate Class A Community/Ambulatory pharmacy permit is not required. However, a specialized permit classification would be required for any specialty pharmacy services (e.g., Class D-Non-sterile Compounding, Class H-Sterile Compounding, Class J-Shared Services).
Hospital clinics/facilities eligible for a Class-B permit may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements (this list is not exhaustive). The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board’s jurisdiction. Applicants should consult with legal counsel to determine if a hospital clinic/facility is under “common control, management or ownership of the same hospital or hospital system.” The Board cannot provide legal advice.

Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses. (See C.4 for non-dispensing activities outside of a pharmacy).

CLASS-B LICENSIURE FOR MISSOURI HOSPITALS

Under Chapter 197, RSMo, DHSS has regulatory jurisdiction over pharmacy services provided within the “licensed premises” of a Missouri hospital. A Class-B Hospital Pharmacy permit is not required for hospitals “solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by” DHSS. [§ 338.220.6, RSMo]. Hospitals solely providing pharmacy services under DHSS’ jurisdiction may choose to be licensed as a Class-B pharmacy although not required.

Section 197.052, RSMo, defines the hospital premises as: “tracts of property which are adjacent but for a common street, single intersection, or highway, as defined in section 300.010, and its accompanying public right-of-way.” Licensees should contact DHSS and their legal counsel to determine what areas are under DHSS’ jurisdiction. The Board cannot provide legal advice.

DHSS has advised that inclusion in the hospital premises is not automatic. Instead, buildings/areas must be officially designated with DHSS as part of the hospital’s license. According to DHSS, this may be done in the hospital’s initial DHSS license application or hospitals may separately notify DHSS to amend their license. Hospitals should contact DHSS to verify that all desired buildings/areas have been properly designated, including any newly added facilities. Pharmacy services provided in buildings/areas that have not been officially included as part of the DHSS licensed hospital premises would be regulated by the Board.

The Board is aware of dually operating Class-B pharmacies providing pharmacy services under DHSS’ jurisdiction and pharmacy services under the Board’s jurisdiction at the same location. Class-B pharmacies may share pharmacy space with a DHSS regulated hospital; the Board does not require physical separation of facilities or drug inventory. However, proper security must be maintained over drug stock at all times. Additionally, pharmacy services under the Board’s jurisdiction must comply with all applicable Board statutes/rules.

AUTHORIZED CLASS-B ACTIVITIES

Section 338.220, RSMo, grants two specific allowances to Class B Hospital pharmacies:

1) Class B Hospital pharmacies may dispense medication by prescription or by “medication order”; and
2) Class B Hospital pharmacies may distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

DISPENSING BY PRESCRIPTION/MEDICATION ORDER

Section 338.220 authorizes Class-B pharmacies to dispense medication pursuant to a patient-specific prescription or
a patient-specific medication order. Prescriptions must comply with all state and federal requirements. A “medication order” is defined as an order for a legend drug or device that is:

1. Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee, and

2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized designee at a hospital or a “hospital clinic or facility” that is under the “common control, management or ownership of the same hospital or hospital system.” [Section 338.165.1] A qualifying hospital clinic or facility could include offsite physician clinics, urgent-care centers, long-term care facilities, infusion clinics, physical therapy units or other healthcare facilities, provided the clinic or facility is under common control, management or ownership of the same hospital or hospital system.

Missouri law is silent on a pharmacist’s authority to perform generic or biosimilar substitution on a medication order. Please consult an attorney for guidance. Medication orders must comply with all state/federal controlled substance requirements.

LABELING

Labeling must comply with § 338.059, RSMo (see H.3). The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite administration to a patient. The Board intends on addressing this issue by rule in the future. In the interim, Board Inspectors will not cite Class-B pharmacies for violations of § 338.059’s labeling requirements if:

1) Medication is given to a healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy or within the licensed premises of a DHSS licensed hospital, and

2) The medication/prescription container labeling is accurate and complies with DHSS’ medication labeling requirements, and

3) The medication/prescription container is not “given to the patient for use/administration” offsite. The Board will not consider medication to have been given to the patient for offsite use/administration if administration is initiated onsite but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.

DISTRIBUTION WITHOUT A MISSOURI DRUG DISTRIBUTOR LICENSE

Section § 338.165.6 provides a Class B Hospital pharmacy may distribute medication to a “hospital clinic or facility” for patient care or treatment without a Missouri drug distributor license. Once again, a “hospital clinic or facility” is defined as a clinic or facility under common control, management or ownership of the same hospital or hospital system. Although a Missouri drug distributor license is not required, pharmacies may still be required to register with the DEA as a controlled substances distributor under federal law if the total dosage units of all controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed during the previous calendar year. Note: Controlled substances may only be distributed to a controlled substances registrant with a BNDD and DEA registration number and via invoice, or for C-IIs, via CSOS or a DEA-222 form.

A Class B pharmacy may not distribute compounded preparations to other entities or compound for office stock. However, an FDA registered drug manufacturer or a 503(b) drug outsourcing facility may provide compounded preparations for office use, provided the entity is also licensed as a Missouri drug distributor (for manufacturers) or a Missouri drug outsourcer (for 503(b) drug outsourcing facilities). (See I.2 for additional information)

RECORD-KEEPING

Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. The Board has determined that Class-B pharmacies may maintain dispensing, distribution and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the
records must be readily retrievable on inspection or if requested by the Board. Note: Controlled substance records must still be separately maintained/retrievable as required by state/federal law.

D.10 CLASS-E RADIOPHARMACEUTICALS (NUCLEAR)

A Class-E Radiopharmaceuticals pharmacy permit is required for any location where radioactive drugs and legend chemicals are compounded, dispensed, stored or sold (radiopharmaceuticals). [20 CSR 2220-2.500] To be eligible for licensure, the applicant must hold a current Nuclear Regulatory Commission (NRC) license. Additionally, a Missouri drug distributor license is required for nuclear pharmacies providing non-patient nuclear preparations for a prescriber’s use. (The Missouri Dept. of Health no longer licenses nuclear pharmacies.)

A Class-E permit is not required for nuclear medicine facilities of hospitals or clinics where radiopharmaceuticals are compounded and dispensed under the supervision of a licensed physician authorized by the NRC or the Missouri Department of Health.

Licensees should review 20 CSR 2220-2.500 in its entirety to ensure compliance. As reflected in the rule, Class-E pharmacies must be under the supervision of a qualified nuclear pharmacist who holds a Missouri pharmacist license and who:

- Is certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or
- Meets the NRC’s training standards for an authorized nuclear pharmacist or an authorized user of radioactive material.

The Board is in the process of updating and revising its Class-E rule. Interested parties should monitor the Board’s website for additional information.

D.11 CLASS-J SHARED SERVICES

A Class-J Shared Services pharmacy permit is required if two (2) or more pharmacies are engaged in, or have an arrangement to provide, functions related to the practice of pharmacy for or on behalf of the other pharmacy. Shared service activities that require a Class-J permit include, but are not limited to:

- Receiving prescriptions/medication orders
- Prescription/order clarification or modification,
- Obtaining prescriber authorization,
- Data entry
- Compounding
- Dispensing
- Pharmacist verification
- Patient counseling,
- Patient profile maintenance
- Medication therapy services
- Medication administration
- Drug utilization review or
- Obtaining refill authorization.

To participate in a Class-J shared services arrangement both pharmacies must:

1) Have a separate Class-J pharmacy permit for each shared services location; and
2) Have the same owner or have a written contract outlining the shared services to be provided by each party and each party’s responsibilities; and
3) Either share a common electronic database or have real time, on-line access to each pharmacy’s electronic medication/prescription records that allows both pharmacies to access the patient’s complete profile.

Each pharmacy participating in a shared service arrangement must have a Class-J permit. Additionally, both pharmacies must maintain a policy and procedure manual that includes:
The Missouri Hospital Advisory Committee 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 it was discussed.

**Committee Members Present**
Greg Teale, R.Ph., Chairman  
Daniel Good, R.Ph., Member  
Nathan Hanson, R.Ph., Member  
David Wolfrath, R.Ph., Member

**Board Members/Staff Present**
Christian Tadrus, Board President  
James Gray, R.Ph., Board Member  
Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector  
Katie DeBold, Inspector

**Others Present**
Michael Boeger, Missouri Bureau of Narcotics and Dangerous Drugs  
Ron Fitzwater, Missouri Pharmacy Association  
Richard Grindstaff, Missouri Dept. of Health and Senior Services  
Sarah Willson, Missouri Hospital Association

Chairman Teale opened the meeting at approximately 9:02 a.m. and roll-call was taken.

**Agenda Item # 2 (Hospital Advisory Committee Members/Vacant Seats):**

**DISCUSSION:** Chairman Teale reported the previously scheduled Jefferson City meeting was changed to a conference call because of multiple Committee vacancies. Specifically, two Committee vacancies exist due to James Gray and Colby Grove being appointed to the Board. Mr. Teale noted both vacant positions are subject to DHSS appointment.
Kimberly Grinston reported suggested candidates have been forwarded to DHSS for review. Richard Grindstaff stated DHSS will be working on filling the vacancies.

**Agenda Item # 6 (Discussion of Patient Home Medications in a Hospital):** Sarah Willson stated questions have been raised regarding compliance requirements for controlled substances brought into the hospital by a patient. Mrs. Willson reported most hospitals don’t allow the practice but asked if a hospital could destroy the medication; further guidance was requested on handling controlled substances known to be obtained illegally. Michael Boeger (BNDD Director) provided the following information:

- Under current law, hospitals can decide if a patient is allowed to bring in their own medication.
- For controlled substances: If the patient is a minor, the medication can be returned to the patient’s parent or caregiver. If the patient is deceased, the medication needs to be destroyed and cannot be given to a family member or caregiver because it was not dispensed to them as the patient.
- If the patient fails to claim or retrieve controlled medication, the medication should be treated as abandoned property and destroyed. The medication cannot be used or dispensed to other patients.
- For illegal drugs, Mr. Boeger noted Missouri law is not definitive. Some hospitals may call the police for destruction while others may inform the patient the medication cannot be brought onto the hospital’s premises. Questions were asked regarding potential EMTALA concerns; Mr. Boeger stated he is unaware of any issues being raised.
- Controlled substances have to be destroyed in compliance with state and federal law and the hospital’s policies/procedures.

Committee discussion held; Sarah Willson asked if hospitals need to log controlled substances brought in by a patient. Mr. Boeger indicated the pharmacy could keep a separate log or note it in the patient’s chart. Nathan Hanson suggested hospitals could also use DEA form 41 or use a reverse distributor. Greg Teale suggested circulating guidance for Missouri hospitals; Sarah Willson agreed to circulate draft guidance language that includes cites to CMS’ conditions of participation.

**Agenda Item # 3 (Board Updates):** Kimberly Grinston reported the Board will be reviewing Chapter 338 throughout 2019 to incorporate standards of practice and is also considering an automated dispensing rule for ambulatory settings.

Ron Fitzwater reported MPA approved a draft legislative proposal that would grant pharmacist prescribing authority. The proposed language is under review by potential bill sponsors and has also been circulated to the medical associations. Preliminary requests have been made to narrow the proposals to specific disease states, such as asthma or diabetes. MPA will likely file a separate proposal that grants pharmacist authority to prescribe tobacco cessation products. A proposed pharmacy technician expanded scope of practice bill is also under review.
Sarah Willson said she was unaware that scope of practice language was submitted to legislators for review and indicated she was under the impression MPA was in the process of working with MHA to address concerns. Mrs. Willson asked if MPA had a sponsor for the pharmacy technician proposal; Mr. Fitzwater stated a sponsor hasn’t been confirmed although discussions are ongoing.

**Agenda Item # 4 (DHSS Updates):** Richard Grindstaff reported MHA provided additional comments on DHSS’ proposed hospital pharmacy rules on January 14, 2019. DHSS will be meeting with general counsel to discuss finalizing the rules for submission to the Governor’s Office shortly.

Nathan Hanson asked if MHA made significant changes to the proposed rules; Sarah Willson indicated no changes were made to the hospital pharmacy rules, however, changes were submitted on administration of the licensing program.

**Agenda Item # 5 (Missouri Hospital Association Updates):** Sarah Willson stated the technician scope of practice legislation is on MHA’s priority list; MHA will be monitoring 2019 legislative proposals for potential impact on Missouri hospitals and reimbursement.

**Agenda Item # 7 (Pharmacist Administration in Hospital/Acute Care Settings):** Sarah Willson indicated confusion still exists on pharmacist administration of medication within a hospital and whether administration is within a pharmacist’s scope of practice. Tom Glenski advised DHSS would have jurisdiction over administration within the licensed hospital premises. Mrs. Willson questioned if pharmacist scope of practice was a Board or DHSS issue. Richard Grindstaff agreed to research the issue for discussion at a future meeting.

**Agenda Item # 8 (Non-Sterile Packaging in Clinics)-** Tom Glenski reported the FDA advised a hospital owned distributor engaged in non-sterile repackaging that a federal repackaging registration was no longer required. Mr. Glenski stated he is unsure how the FDA’s letter impacts other hospitals and suggested MHA or another group ask for official clarification. Committee members asked about state regulation of repackagers; Mr. Glenski indicated the Board’s rules exempt hospitals from having a drug distributor license if medication is distributed within the hospital system. However, the Board’s repackaging rules would apply if repackaged medication is dispensed by a Class-B pharmacy or outside of the hospital. Committee consensus to discuss potential guidance language at a future meeting.

**Agenda Item # 9 (2019 Discussion Items):** Committee discussion held; Consensus to discuss the following additional items at a future meeting:
- Non-Class B hospital guidance
- Automated/technology assisted verification
- Clinic administration of patient owned sterile compounds that include controlled substances
Committee discussion held on discussing medical marijuana at a future meeting; Sarah Willson reported MHA submitted correspondence to DHSS asking that hospitals not be referenced in the required medical marijuana rules. Mrs. Willson noted hospitals have to annually certify they are in compliance with federal law which they may not be able to do if marijuana is allowed on-site.

**Agenda Item # 10 (Future Meeting Dates/Topics)** - Committee Consensus to meet on March 1, 2019.

THE MEETING WAS ADJOURNED BY CONSENSUS AT 10:55 A.M.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
   a. SB 357 (RPh Scope of Practice)
   b. SB 127 (Importation Study)
   c. SB 274 (Pharmacy Pilot Projects)
   d. SB 309 (Tobacco Cessation)
   e. SB 155 (PDMP)
   f. HB 257 (Bd. Disc. Agreements)
   g. HB 293 (E-Prescribing)
   h. HB 487 (Contraceptives)
   i. HB 667 (Foreign Distributors)
   j. HB 727 (Dispensing on Hospital Discharge)
AN ACT
To repeal section 338.010, RSMo, and to enact in lieu thereof one new section relating
to the practice of pharmacy.

Section A. Section 338.010, RSMo, is repealed and one new section
enacted in lieu thereof, to be known as section 338.010, to read as follows:

338.010. 1. The "practice of pharmacy" means the interpretation,
implementation, and evaluation of medical prescription orders, including any
legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of
such orders or facilitating the dispensing of such orders; the designing, initiating,
implementing, and monitoring of a medication therapeutic plan as defined by the
prescription order so long as the prescription order is specific to each patient for
care by a pharmacist; the compounding, dispensing, labeling, and administration
of drugs and devices pursuant to medical prescription orders and administration
of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria,
tetanus, pertussis, and meningitis vaccines by written protocol authorized by a
physician for persons at least seven years of age or the age recommended by the
Centers for Disease Control and Prevention, whichever is higher, or the
administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria,
tetanus, pertussis, meningitis, and viral influenza vaccines by written protocol
authorized by a physician for a specific patient as authorized by rule; the
participation in drug selection according to state law and participation in drug
utilization reviews; the proper and safe storage of drugs and devices and the
maintenance of proper records thereof; consultation with patients and other
health care practitioners, and veterinarians and their clients about legend drugs,
about the safe and effective use of drugs and devices; [and] the offering or
performing of those acts, services, operations, or transactions necessary in the

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is
intended to be omitted in the law.
conduct, operation, management and control of a pharmacy; and the provision of medication therapy services, including authority to prescribe drugs and controlled substances, according to a written medication therapy services protocol. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

2. Any pharmacist who [accepts a prescription order for a medication therapeutic plan] provides medication therapy services shall have a written medication therapy services protocol from the physician [who refers the patient for medication therapy services]. The written medication therapy services protocol [and the prescription order for a medication therapeutic plan] shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or an assistant physician in accordance with section 334.037 or from a physician assistant engaged in a supervision agreement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication [therapeutic] therapy services.

6. This section shall not be construed to allow a pharmacist to diagnose [or independently prescribe pharmaceuticals].
7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols [for prescription orders] for medication therapy services and administration of viral [influenza] vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. 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, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication [therapeutic plan] therapy services authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication [therapeutic plan] therapy services authority may engage in the [designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist] provision of medication therapy services.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written medication therapy services protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of
veterinary medicine"), "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

12. In addition to other requirements established by the joint promulgation of rules by the board of pharmacy and the state board of registration for the healing arts:

(1) A pharmacist shall administer vaccines by protocol in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);

(2) A pharmacist who is administering a vaccine shall request a patient to remain in the pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions. Such pharmacist shall have adopted emergency treatment protocols;

(3) In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon completion, and shall display the certification in his or her pharmacy where vaccines are delivered.

13. A pharmacist shall inform the patient that the administration of the vaccine will be entered into the ShowMeVax system, as administered by the department of health and senior services. The patient shall attest to the inclusion of such information in the system by signing a form provided by the pharmacist. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient's primary health care provider, if provided by the patient, containing:

(1) The identity of the patient;

(2) The identity of the vaccine or vaccines administered;

(3) The route of administration;

(4) The anatomic site of the administration;

(5) The dose administered; and

(6) The date of administration.
AN ACT

To amend chapter 192, RSMo, by adding thereto one new section relating to a prescription drug importation study.

Section A. Chapter 192, RSMo, is amended by adding thereto one new section, to be known as section 192.340, to read as follows:

192.340. The department of health and senior services shall conduct a study regarding the processes by which the state may import certain prescription drugs from other countries for eventual consumption by Missouri consumers. The department shall:

(1) Determine how the state may become certified by the U.S. Secretary of Health and Human Services to operate a prescription drug importation program;

(2) Determine how to ensure that only drugs meeting U.S. Food and Drug Administration safety, effectiveness, and other standards are imported by the state;

(3) Identify prescription drugs with the highest potential for consumer savings through importation;

(4) Estimate potential consumer savings attributable to importation;

(5) Determine with whom the state could contract to distribute imported drugs;

(6) Determine how to limit the distribution of imported drugs to only Missouri consumers who would benefit most from the associated savings;

(7) Consult with the Missouri state board of registration for the healing arts, representatives of the pharmaceutical industry, patient
advocates, and others representing persons who could be affected by importation; and

(8) Propose changes, if necessary, to state statutes and regulations to facilitate importation by the state.

The department shall report the study's findings and recommendations to the general assembly by December 31, 2020.

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AN ACT

To amend chapter 338, RSMo, by adding thereto one new section relating to board of pharmacy pilot programs.

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

Section A. Chapter 338, RSMo, is amended by adding thereto one new section, to be known as section 338.143, to read as follows:

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

(1) "Remote medication dispensing", dispensing or assisting in the dispensing of medication outside of a licensed pharmacy;

(2) "Technology assisted verification", the verification of medication or prescription information using a combination of scanning technology and visual confirmation by a pharmacist.

2. The board of pharmacy may approve, modify, and establish requirements for pharmacy pilot or demonstration research projects related to technology assisted verification or remote medication dispensing that are designed to enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services.

3. To be approved, pilot or research projects shall be within the scope of the practice of pharmacy as defined by chapter 228, be under the supervision of a Missouri licensed pharmacist, and comply with applicable compliance and reporting as established by the board by rule, including any staff training or education requirements. Board approval shall be limited to a period of up to eighteen months, provided the board grant an additional six month extension if deemed necessary or appropriate to gather or complete research data or if deemed in the best interests of the patient. The board may rescind approval of a pilot
22 project at any time if deemed necessary or appropriate in the interest
23 of patient safety.
24
4. The provisions of this subsection shall expire on August 28, 2023. The board shall provide a final report on approved projects and
26 related data or findings to the general assembly on or before December
27 31, 2022. The name, location, approval dates, general description of and
28 responsible pharmacist for an approved pilot or research project shall
29 be deemed an open record.

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AN ACT

To repeal section 338.010, RSMo, and to enact in lieu thereof two new sections relating to the prescriptive authority of pharmacists.

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

Section A. Section 338.010, RSMo, is repealed and two new sections enacted in lieu thereof, to be known as sections 338.010 and 338.665, to read as follows:

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons at least seven years of age or the age recommended by the Centers for Disease Control and Prevention, whichever is higher, or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, meningitis, and viral influenza vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs,
about the safe and effective use of drugs and devices; the prescribing and
dispensing of any tobacco cessation product under section 338.665; and
the offering or performing of those acts, services, operations, or transactions
necessary in the conduct, operation, management and control of a pharmacy. No
person shall engage in the practice of pharmacy unless he is licensed under the
provisions of this chapter. This chapter shall not be construed to prohibit the use
of auxiliary personnel under the direct supervision of a pharmacist from assisting
the pharmacist in any of his or her duties. This assistance in no way is intended
to relieve the pharmacist from his or her responsibilities for compliance with this
chapter and he or she will be responsible for the actions of the auxiliary
personnel acting in his or her assistance. This chapter shall also not be
construed to prohibit or interfere with any legally registered practitioner of
medicine, dentistry, or podiatry, or veterinary medicine only for use in animals,
or the practice of optometry in accordance with and as provided in sections
195.070 and 336.220 in the compounding, administering, prescribing, or
dispensing of his or her own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication
therapeutic plan shall have a written protocol from the physician who refers the
patient for medication therapy services. The written protocol and the prescription
order for a medication therapeutic plan shall come from the physician only, and
shall not come from a nurse engaged in a collaborative practice arrangement
under section 334.104, or from a physician assistant engaged in a supervision
agreement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person,
firm or corporation from owning a pharmacy regulated by sections 338.210 to
338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with
the sale of nonprescription drugs and the ordinary household remedies and such
drugs or medicines as are normally sold by those engaged in the sale of general
merchandise.

5. No health carrier as defined in chapter 376 shall require any physician
with which they contract to enter into a written protocol with a pharmacist for
medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose
or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section
and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. 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, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary
medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

12. In addition to other requirements established by the joint promulgation of rules by the board of pharmacy and the state board of registration for the healing arts:

(1) A pharmacist shall administer vaccines by protocol in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);

(2) A pharmacist who is administering a vaccine shall request a patient to remain in the pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions. Such pharmacist shall have adopted emergency treatment protocols;

(3) In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon completion, and shall display the certification in his or her pharmacy where vaccines are delivered.

13. A pharmacist shall inform the patient that the administration of the vaccine will be entered into the ShowMeVax system, as administered by the department of health and senior services. The patient shall attest to the inclusion of such information in the system by signing a form provided by the pharmacist. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient's primary health care provider, if provided by the patient, containing:

(1) The identity of the patient;
(2) The identity of the vaccine or vaccines administered;
(3) The route of administration;
(4) The anatomic site of the administration;
(5) The dose administered; and
(6) The date of administration.

338.665. 1. For purposes of this chapter, "tobacco cessation product" means any drug approved by the federal Food and Drug Administration for use as an aid to tobacco cessation.

2. The board of pharmacy shall promulgate regulations governing a pharmacist's authority to prescribe and dispense tobacco
cessation products. The regulations for pharmacist prescribing and dispensing shall include the conditions for which a pharmacist may prescribe and dispense a tobacco cessation product.

3. 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, 2019, shall be invalid and void.
AN ACT

To amend chapter 195, RSMo, by adding thereto six new sections relating to the monitoring of certain prescribed controlled substances, with penalty provisions.

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

Section A. Chapter 195, RSMo, is amended by adding thereto six new sections, to be known as sections 195.450, 195.453, 195.456, 195.459, 195.462, and 195.465, to read as follows:

195.450. 1. Sections 195.450 to 195.465 shall be known and may be cited as the "Narcotics Control Act".

2. As used in sections 195.450 to 195.465, the following terms shall mean:

(1) "Controlled substance", the same meaning as given such term in section 195.010;

(2) "Department", the department of health and senior services;

(3) "Dispenser", a person who delivers a Schedule II, III, or IV controlled substance to a patient, but does not include:

(a) A hospital, as defined in section 197.020, that distributes such substances for the purpose of inpatient care or dispenses prescriptions for controlled substance at the time of discharge from such facility;

(b) A practitioner or other authorized person who administers such a substance; or

(c) A wholesale distributor of a controlled substance;

(4) "Patient", a person who is an ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed, not including a hospice patient enrolled in a Medicare-certified hospice program who has controlled substances dispensed to him or her by such hospice program;
(5) "Schedule II, III, or IV controlled substance", a controlled substance that is listed in Schedule II, III, or IV of the schedules provided under this chapter or the Controlled Substances Act, 21 U.S.C. Section 812.

3. The provisions of sections 195.450 to 195.465 shall not apply to persons licensed under chapter 340.

195.453. 1. The department shall establish and maintain a narcotics control program for the monitoring of prescribing and dispensing all Schedule II, III, and IV controlled substances by professionals licensed to prescribe or dispense such substances in this state. The funding of the narcotics control program shall be subject to appropriations. In addition to appropriations from the general assembly, the department may apply for available grants and shall be able to accept other gifts, grants, and donations to develop and maintain the program.

2. Each dispenser shall submit to the department by electronic means information regarding each dispensation of a drug included in subsection 1 of this section. The information submitted for each dispensation shall include:

   (1) The pharmacy's Drug Enforcement Agency (DEA) number;
   (2) The date of the prescription;
   (3) The following, if there is a prescription:
      (a) The prescription number or other unique identifier;
      (b) Whether the prescription is new or a refill; and
      (c) The prescriber's DEA or National Provider Identification (NPI) number;
   (4) The National Drug Code (NDC) for the drug dispensed;
   (5) The quantity and dosage of the drug dispensed;
   (6) The patient's identification number including, but not limited to, any one of the following:
      (a) The patient's drivers license number;
      (b) The patient's government-issued identification number; or
      (c) The patient's insurance cardholder identification number;
   and
   (7) The patient's name, address, and date of birth.

The addition of any further information to the list of data required to be submitted in this subsection shall be the sole purview of the general
 assembly.

3. Each dispenser shall submit the information in accordance with transmission standards established by the American Society for Automation in Pharmacy or any successor organization and shall report data within twenty-four hours of dispensation. Beginning January 1, 2021, the department shall begin phasing in a requirement that dispensers report data in real time with all report data to be submitted in real time by January 1, 2022.

4. (1) The department may issue a waiver to a dispenser who is unable to submit the dispensation information by electronic means. Such waiver may permit the dispenser to submit dispensation information by paper form or other means, provided all information required in subsection 2 of this section is submitted in such alternative format.

(2) The department may grant an extension to dispensers who are temporarily unable to electronically submit the dispensation information required in subsection 2 of this section in accordance with the time frame established in subsection 3 of this section due to unforeseen circumstances. In cases in which an extension is granted, dispensers shall be responsible for reporting the required data in a subsequent transmission.

195.456. 1. Dispensation information submitted to the department shall be confidential and not subject to public disclosure under chapter 610 except as provided in subsections 3 to 5 of this section.

2. The department shall maintain procedures to ensure that the privacy and confidentiality of patients and personal information collected, recorded, transmitted, and maintained are not disclosed to persons except as provided in subsections 3 to 5 of this section.

3. The department shall review the dispensation information and, if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the department shall notify the appropriate law enforcement or professional licensing board, and provide any dispensation information required for an investigation.

4. The department may provide data in the narcotics control program to the following persons:
(1) Persons both in-state and out-of-state authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients;

(2) An individual who requests his or her own dispensation information in accordance with state law;

(3) Any state board charged with regulating a professional who has the authority to prescribe or dispense controlled substances that requests data related to a specific professional under the authority of such board if such board has a current and open investigation into such professional and the data is limited to such professional;

(4) Local, state, and federal law enforcement or prosecutorial officials, both in-state and out-of-state, engaged in the investigation or enforcement of the laws governing prescription drugs only when based on a specific case and under a subpoena or court order issued by a court of competent jurisdiction; and

(5) The MO HealthNet division within the department of social services regarding MO HealthNet program recipients.

5. The department may provide data to public or private entities for statistical, research, or educational purposes only after removing information that could be used to identify individual patients, prescribers, dispensers, or persons who received dispensations from dispensers.

6. Nothing in sections 195.450 to 195.465 shall be construed to require a pharmacist or prescriber to obtain information about a patient from the database.

7. No dispensation information submitted to the department shall be used by any local, state, or federal authority to prevent an individual from owning or obtaining a firearm.

8. No dispensation information submitted to the department shall be the sole basis for probable cause to obtain an arrest or search warrant as part of a criminal investigation.

9. Beginning August 28, 2021, the department shall maintain an individual's prescription and dispensation information obtained under sections 195.450 to 195.465 for a maximum of three years from the date of dispensation, after which such information shall be deleted from the program.

195.459. 1. The department is authorized to contract with any
other agency of this state, a political subdivision of this state, any other
state with a private vendor, or any state government that currently
operates a narcotics control program. Any contractor shall comply
with the provisions regarding confidentiality or prescription
information in section 195.456.

2. If a political subdivision of this state is operating a narcotics
control program, the political subdivision’s program shall be permitted
to continue operating until such time as the department's program is
available for utilization by prescribers and dispensers throughout the
state.

195.462. The department shall promulgate rules setting forth the
procedures and methods of implementing sections 195.450 to
195.465. 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 powers vested in
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, 2019, shall be invalid and void.

195.465. 1. A dispenser who knowingly fails to submit
dispensation information to the department as required in sections
195.450 to 195.465 or knowingly submits the incorrect dispensation
information shall be subject to an administrative penalty in the amount
of one thousand dollars for each violation. The penalty shall be
assessed through an order issued by the director of the
department. Any person subject to an administrative penalty may
appeal to the administrative hearing commission under the provisions
of chapter 621.

2. Any person who unlawfully or knowingly accesses or discloses,
or any person authorized to have prescription or dispensation
information under sections 195.450 to 195.465 who knowingly discloses
such information in violation of sections 195.450 to 195.465 or
knowingly uses such information in a manner and for a purpose in
violation of sections 195.450 to 195.465 is guilty of a class E felony.
AN ACT

To repeal section 338.140, RSMo, and to enact in lieu thereof one new section relating to the scope of disciplinary procedure of the board of pharmacy.

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

Section A. Section 338.140, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 338.140, to read as follows:

338.140. 1. The board of pharmacy shall have a common seal, and shall have power to adopt such rules and bylaws not inconsistent with law as may be necessary for the regulation of its proceedings and for the discharge of the duties imposed pursuant to sections 338.010 to 338.198, and shall have power to employ an attorney to conduct prosecutions or to assist in the conduct of prosecutions pursuant to sections 338.010 to 338.198.

2. The board shall keep a record of its proceedings.

3. The board of pharmacy shall make annually to the governor and, upon written request, to persons licensed pursuant to the provisions of this chapter a written report of its proceedings.

4. The board of pharmacy shall appoint an advisory committee composed of six members, one of whom shall be a representative of pharmacy but who shall not be a member of the pharmacy board, three of whom shall be representatives of wholesale drug distributors as defined in section 338.330, one of whom shall be a representative of drug manufacturers, and one of whom shall be a licensed veterinarian recommended to the board of pharmacy by the board of veterinary medicine. The committee shall review and make recommendations to the board on the merit of all rules and regulations dealing with pharmacy distributors, wholesale drug distributors, drug manufacturers, and veterinary legend drugs which are proposed by the board.

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.
5. A majority of the board shall constitute a quorum for the transaction of business.

6. Notwithstanding any other provisions of law to the contrary, the board may issue letters of reprimand, censure or warning to any holder of a license or registration required pursuant to this chapter for any violations that could result in disciplinary action as defined in section 338.055. Alternatively, at the discretion of the board, the board may enter into a voluntary compliance agreement with a licensee, permit holder, or registrant to ensure or promote compliance with chapter 338 and the rules of the board, in lieu of board discipline. The agreement shall be a public record. The time limitation identified in section 324.043 for commencing a disciplinary proceeding shall be tolled while an agreement authorized by this section is in effect.
AN ACT

To repeal sections 195.060, 196.100, 221.111, 338.015, 338.055, and 338.056, RSMo, and to
enact in lieu thereof seven new sections relating to electronic prescriptions, with a
penalty provision.

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

Section A. Sections 195.060, 196.100, 221.111, 338.015, 338.055, and 338.056, RSMo,
are repealed and seven new sections enacted in lieu thereof, to be known as sections 195.060,
195.550, 196.100, 221.111, 338.015, 338.055, and 338.056 to read as follows:

195.060. 1. Except as provided in subsection 4 of this section, a pharmacist, in good
faith, may sell and dispense controlled substances to any person only upon a prescription of a
practitioner as authorized by statute, provided that the controlled substances listed in Schedule
V may be sold without prescription in accordance with regulations of the department of health
and senior services. All written prescriptions shall be signed by the person prescribing the same,
except for electronic prescriptions. All prescriptions shall be dated on the day when issued and
bearing the full name and address of the patient for whom, or of the owner of the animal for
which, the drug is prescribed, and the full name, address, and the registry number under the
federal controlled substances laws of the person prescribing, if he or she is required by those laws
to be so registered. If the prescription is for an animal, it shall state the species of the animal for
which the drug is prescribed. The person filling the prescription shall either write the date of
filling and his or her own signature on the prescription or retain the date of filling and the identity
of the dispenser as electronic prescription information. The prescription or electronic
prescription information shall be retained on file by the proprietor of the pharmacy in which it
is filled for a period of two years, so as to be readily accessible for inspection by any public

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.
officer or employee engaged in the enforcement of this law. No prescription for a drug in Schedule I or II shall be filled more than six months after the date prescribed; no prescription for a drug in Schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date of the original prescription or be refilled more than five times unless renewed by the practitioner.

2. A pharmacist, in good faith, may sell and dispense controlled substances to any person upon a prescription of a practitioner located in another state, provided that the:
   (1) Prescription was issued according to and in compliance with the applicable laws of that state and the United States; and
   (2) Quantity limitations in subsection 4 of section 195.080 apply to prescriptions dispensed to patients located in this state.

3. The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in such drugs, may sell the stock to a manufacturer, wholesaler, or pharmacist, but only on an official written order.

4. A pharmacist, in good faith, may sell and dispense any Schedule II drug or drugs to any person in emergency situations as defined by rule of the department of health and senior services upon an oral prescription by an authorized practitioner.

5. Except where a bona fide physician-patient-pharmacist relationship exists, prescriptions for narcotics or hallucinogenic drugs shall not be delivered to or for an ultimate user or agent by mail or other common carrier.

195.550. 1. Notwithstanding any other provision of this section or any other law to the contrary, beginning August 28, 2020, no person shall issue any prescription in this state unless the prescription is made by electronic prescription from the person issuing the prescription to a pharmacy, except for prescriptions:
   (1) Issued by veterinarians;
   (2) Issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure;
   (3) Issued by a practitioner to be dispensed by a pharmacy located outside the state;
   (4) Issued when the prescriber and dispenser are the same entity;
   (5) Issued that include elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard;
   (6) Issued by a practitioner for a drug that the federal Food and Drug Administration requires the prescription to contain certain elements that are not able to be accomplished with electronic processing;
(7) Issued by a practitioner allowing for the dispensing of a nonpatient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a nonpatient specific prescription;

(8) Issued by a practitioner prescribing a drug under a research protocol;

(9) Issued by practitioners who have received a waiver or a renewal thereof for a specified period determined by the commissioner, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established in regulation by the department of health and senior services, due to economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

(10) Issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to make an electronic prescription as required by this subsection, such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition.

2. A pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription properly falls under one of the exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from otherwise valid written, oral, or fax prescriptions that are consistent with current laws and regulations.

3. An individual who violates this section commits a civil violation for which a fine of two hundred and fifty dollars per violation, not to exceed five thousand dollars per calendar year, may be assessed. The department of health and senior services is responsible for the enforcement of this section.

196.100. 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

2. A drug dispensed on an electronic prescription or a written prescription signed by a licensed physician, dentist, or veterinarian, except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to a diagnosis by mail, shall be exempt from the requirements of this section if such physician, dentist, or veterinarian is licensed by law to administer such drug, and such drug bears a label containing the name and place of business of
the dispenser, the serial number and date of such prescription, and the name of such physician,
dentist, or veterinarian.

3. The department is hereby directed to promulgate regulations exempting from any
labeling or packaging requirement of sections 196.010 to 196.120, drugs and devices which are,
in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial
quantities at establishments other than those where originally processed or packed, on condition
that such drugs and devices are not adulterated or misbranded under the provisions of said
sections upon removal from such processing, labeling, or repacking establishment.

221.111. 1. A person commits the offense of possession of unlawful items in a prison
or jail if such person knowingly delivers, attempts to deliver, possesses, deposits, or conceals in
or about the premises of any correctional center as the term "correctional center" is defined under
section 217.010, or any city, county, or private jail:

   (1) Any controlled substance as that term is defined by law, except upon the written or
electronic prescription of a licensed physician, dentist, or veterinarian;

   (2) Any other alkaloid of any kind or any intoxicating liquor as the term intoxicating
liquor is defined in section 311.020;

   (3) Any article or item of personal property which a prisoner is prohibited by law, by rule
made pursuant to section 221.060, or by regulation of the department of corrections from
receiving or possessing, except as herein provided;

   (4) Any gun, knife, weapon, or other article or item of personal property that may be
used in such manner as to endanger the safety or security of the institution or as to endanger the
life or limb of any prisoner or employee thereof.

2. The violation of subdivision (1) of subsection 1 of this section shall be a class D
felony; the violation of subdivision (2) of this section shall be a class E felony; the violation of
subdivision (3) of this section shall be a class A misdemeanor; and the violation of subdivision
(4) of this section shall be a class B felony.

3. The chief operating officer of a county or city jail or other correctional facility or the
administrator of a private jail may deny visitation privileges to or refer to the county prosecuting
attorney for prosecution any person who knowingly delivers, attempts to deliver, possesses,
deposits, or conceals in or about the premises of such jail or facility any personal item which is
prohibited by rule or regulation of such jail or facility. Such rules or regulations, including a list
of personal items allowed in the jail or facility, shall be prominently posted for viewing both
inside and outside such jail or facility in an area accessible to any visitor, and shall be made
available to any person requesting such rule or regulation. Violation of this subsection shall be
an infraction if not covered by other statutes.
4. Any person who has been found guilty of a violation of subdivision (2) of subsection 1 of this section involving any alkaloid shall be entitled to expunge the record of the violation. The procedure to expunge the record shall be pursuant to section 610.123. The record of any person shall not be expunged if such person has been found guilty of knowingly delivering, attempting to deliver, possessing, depositing, or concealing any alkaloid of any controlled substance in or about the premises of any correctional center, or city or county jail, or private prison or jail.

338.015. 1. The provisions of sections 338.010 to 338.015 shall not be construed to inhibit the patient's freedom of choice to obtain prescription services from any licensed pharmacist. However, nothing in sections 338.010 to 338.315 abrogates the patient's ability to waive freedom of choice under any contract with regard to payment or coverage of prescription expense.

2. All pharmacists may provide pharmaceutical consultation and advice to persons concerning the safe and therapeutic use of their prescription drugs.

3. All patients shall have the right to receive a written prescription from their prescriber to take to the facility of their choice or to have an electronic prescription transmitted to the facility of their choice.

338.055. 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

(1) Use of any controlled substance, as defined in chapter 195, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;

(2) The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud,
dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

(3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;

(4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

(7) Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license, or diploma from any school;

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

(9) A person is finally adjudged incapacitated by a court of competent jurisdiction;

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

(11) Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

(13) Violation of any professional trust or confidence;

(14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

(16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written, electronic, or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided,
however, that nothing contained herein shall prohibit a pharmacist from substituting or changing
the brand of any drug as provided under section 338.056, and any such substituting or changing
of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional
or dishonorable conduct unless a violation of section 338.056 occurs;
(17) Personal use or consumption of any controlled substance unless it is prescribed,
dispensed, or administered by a health care provider who is authorized by law to do so.
3. After the filing of such complaint, the proceedings shall be conducted in accordance
with the provisions of chapter 621. Upon a finding by the administrative hearing commission
that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the
board may, singly or in combination, censure or place the person named in the complaint on
probation on such terms and conditions as the board deems appropriate for a period not to exceed
five years, or may suspend, for a period not to exceed three years, or revoke the license,
certificate, or permit. The board may impose additional discipline on a licensee, registrant, or
permittee found to have violated any disciplinary terms previously imposed under this section
by agreement. The additional discipline may include, singly or in combination, censure, placing
the licensee, registrant, or permittee named in the complaint on additional probation on
such terms and conditions as the board deems appropriate, which additional probation shall not
exceed five years, or suspension for a period not to exceed three years, or revocation of the
license, certificate, or permit.
4. If the board concludes that a licensee or registrant has committed an act or is engaging
in a course of conduct which would be grounds for disciplinary action which constitutes a clear
and present danger to the public health and safety, the board may file a complaint before the
administrative hearing commission requesting an expedited hearing and specifying the activities
which give rise to the danger and the nature of the proposed restriction or suspension of the
licensee's or registrant's license. Within fifteen days after service of the complaint on the
licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing
to determine whether the alleged activities of the licensee or registrant appear to constitute a
clear and present danger to the public health and safety which justify that the licensee's or
registrant's license or registration be immediately restricted or suspended. The burden of proving
that the actions of a licensee or registrant constitute a clear and present danger to the public
health and safety shall be upon the state board of pharmacy. The administrative hearing
commission shall issue its decision immediately after the hearing and shall either grant to the
board the authority to suspend or restrict the license or dismiss the action.
5. If the administrative hearing commission grants temporary authority to the board to
restrict or suspend the licensee's or registrant's license, such temporary authority of the board
shall become final authority if there is no request by the licensee or registrant for a full hearing
within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the licensee or registrant named in the complaint, set a date to hold a full hearing under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed by the board.

6. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

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

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

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

3. No prescription shall be valid without the signature of the prescriber, except an electronic prescription.

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

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

6. Violations of this section are infractions.
AN ACT

To repeal section 338.010, RSMo, and to enact in lieu thereof two new sections relating to contraceptives.

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

Section A. Section 338.010, RSMo, is repealed and two new sections enacted in lieu thereof, to be known as sections 338.010 and 338.720, to read as follows:

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons at least seven years of age or the age recommended by the Centers for Disease Control and Prevention, whichever is higher, or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, meningitis, and viral influenza vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; the dispensing of self-administered oral hormonal contraceptives under section 338.720; and the offering or performing of those acts, services, operations, or

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.
transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a supervision agreement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. 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, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

12. In addition to other requirements established by the joint promulgation of rules by the board of pharmacy and the state board of registration for the healing arts:
   (1) A pharmacist shall administer vaccines by protocol in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);
   (2) A pharmacist who is administering a vaccine shall request a patient to remain in the pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions. Such pharmacist shall have adopted emergency treatment protocols;
   (3) In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon
13. A pharmacist shall inform the patient that the administration of the vaccine will be entered into the ShowMeVax system, as administered by the department of health and senior services. The patient shall attest to the inclusion of such information in the system by signing a form provided by the pharmacist. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient’s primary health care provider, if provided by the patient, containing:

   (1) The identity of the patient;
   (2) The identity of the vaccine or vaccines administered;
   (3) The route of administration;
   (4) The anatomic site of the administration;
   (5) The dose administered; and
   (6) The date of administration.

338.720. 1. For purposes of this section, "self-administered oral hormonal contraceptive" shall mean a drug composed of a combination of hormones that is approved by the Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

2. A pharmacist may dispense self-administered oral hormonal contraceptives to a person who is eighteen years of age or older under a prescription order for medication therapy services as described in section 338.010. A prescription order for a self-administered oral hormonal contraceptive shall have no expiration date.

3. The board of pharmacy, under section 338.140, and the board of registration for the healing arts, under section 334.125, shall jointly promulgate rules regulating the use of protocols for prescription orders for self-administered oral hormonal contraceptives. 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, 2019, shall be invalid and void.

4. The rules adopted under this section shall require a pharmacist to:
(1) Complete a training program approved by the board of pharmacy that is related to prescribing self-administered oral hormonal contraceptives;

(2) Provide a self-screening risk assessment tool that the patient shall use prior to the pharmacist's prescribing the self-administered oral hormonal contraceptive;

(3) At least once every twelve months refer the patient to the patient's primary care practitioner, or women's health care practitioner, or the physician with whom the pharmacist has a prescription order, before dispensing the self-administered oral hormonal contraceptive to the patient;

(4) Provide the patient with a written record of the self-administered oral hormonal contraceptive dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and

(5) Dispense the self-administered oral hormonal contraceptive to the patient as soon as practicable.

5. All state and federal laws governing insurance coverage of contraceptive drugs, devices, products, and services shall apply to self-administered oral hormonal contraceptives dispensed by a pharmacist under this section.

6. The provisions of this section shall terminate upon the enactment of any laws allowing the provision of oral hormonal contraceptives from a pharmacist without a prescription.

7. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's written prescription order.
AN ACT


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


195.422. No state official or law enforcement officer shall impede or inhibit the importation of a prescription drug for personal use so long as the patient has a valid prescription from a prescriber.

338.222. The board shall allow a pharmacy located in a country outside of the United States to be licensed in this state if such pharmacy is licensed in its local jurisdiction under legal standards comparable to those that are to be met by a pharmacy in this state.

338.240. 1. Upon evidence satisfactory to the said Missouri board of pharmacy:

(1) That the pharmacy for which a permit, or renewal thereof, is sought, will be conducted in full compliance with sections 338.210 to 338.300, with existing laws, and with the rules and regulations as established hereunder by said board;

(2) That the equipment and facilities of such pharmacy are such that it can be operated in a manner not to endanger the public health or safety;

(3) That such pharmacy is equipped with proper pharmaceutical and sanitary appliances and kept in a clean, sanitary and orderly manner;

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.
(4) That the management of said pharmacy is under the supervision of either a registered pharmacist, or an owner or employee of the owner, who has at his or her place of business a registered pharmacist employed for the purpose of compounding physician's or veterinarian's prescriptions in the event any such prescriptions are compounded or sold;

(5) That said pharmacy is operated in compliance with the rules and regulations legally prescribed with respect thereto by the Missouri board of pharmacy, a permit or renewal thereof shall be issued to such persons as the said board of pharmacy shall deem qualified to conduct such pharmacy.

2. In lieu of a registered pharmacist as required by subdivision (4) of subsection 1 of this section, a pharmacy permit holder that only holds a class L veterinary permit and no other pharmacy permit may designate a supervising registered pharmacist who shall be responsible for reviewing the activities and records of the class L pharmacy permit holder as established by the board by rule. The supervising registered pharmacist shall not be required to be physically present on site during the business operations of a class L pharmacy permit holder identified in subdivision (5) of subsection 1 of this section when noncontrolled legend drugs under 21 U.S.C. Section 353 are being dispensed for use in animals, but shall be specifically present on site when any noncontrolled drugs for use in animals are being compounded.

3. If practicable and if it would maintain the board's ability to uphold the public health or safety of a patient, for any pharmacy located outside of the United States, the board shall allow any evidence required under subsection 1 of this section to be provided electronically.

338.250. No pharmacy shall be licensed under the provisions of this chapter unless it is equipped with proper pharmaceutical equipment and reference manuals, so that the practice of pharmacy may be accurately and properly performed. The board shall prescribe the minimum of technical equipment which the pharmacy shall at all times possess. Such requirements may vary, depending upon the population served, but shall be consistently and uniformly enforced. No permit shall be issued or renewed for the operation of a pharmacy unless the pharmacy shall be operated in a manner and according to the rules and regulations prescribed by law and by the Missouri board of pharmacy with respect to obtaining and maintaining such a permit. Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as drug laws of this state and federal drug laws of the United States on all drugs received or possessed, including but not limited to drugs and devices received or possessed pursuant to a consignment arrangement.

338.270. 1. Application blanks for renewal permits shall be mailed to each permittee on or before the first day of the month in which the permit expires and, if application for renewal of permit is not made before the first day of the following month, the existing permit, or renewal
thereof, shall lapse and become null and void upon the last day of that month. If a pharmacy is located outside of the United States, the application for a renewal permit may be sent electronically under the time frame provided for in this subsection.

2. The board of pharmacy shall not renew a nonresident pharmacy license if the renewal applicant does not hold a current pharmacy license or its equivalent in the state in which the nonresident pharmacy is located. As used in this subsection, "nonresident pharmacy" also includes any pharmacy located outside of the United States.

338.315. 1. Except as otherwise provided by the board by rule, it shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs under 21 U.S.C. Section 353 from other than a licensed or registered drug distributor, drug outsourcer, third-party logistics provider, or licensed pharmacy. A drug distributor, drug outsourcer, third-party logistics provider, or pharmacy possessing a valid license or registration granted by another country located outside of the United States under legal standards comparable to those that are to be met by a drug distributor, drug outsourcer, third-party logistics provider, or pharmacy provider of this state is sufficient to satisfy the requirements of this section. Any person who violates the provisions of this section shall, upon conviction, be adjudged guilty of a class A misdemeanor. Any subsequent conviction shall constitute a class E felony.

2. Notwithstanding any other provision of law to the contrary, the sale, purchase, or trade of a prescription drug by a pharmacy to other pharmacies is permissible if the total dollar volume of such sales, purchases, or trades are in compliance with the rules of the board and do not exceed five percent of the pharmacy's total annual prescription drug sales.

3. Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Such records shall be maintained for two years and be readily available upon request by the board or its representatives.

4. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2012, shall be invalid and void.

338.333. 1. Except as otherwise provided by the board of pharmacy by rule in the event of an emergency or to alleviate a supply shortage, no person or distribution outlet shall act as a
wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. The board may grant temporary licenses when the wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider first applies for a license to operate within the state. Temporary licenses shall remain valid until such time as the board shall find that the applicant meets or fails to meet the requirements for regular licensure. No license shall be issued or renewed for a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider, unless such drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider meets the requirements of section 338.335.

2. An agent or employee of any licensed or registered wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider need not seek licensure under this section and may lawfully possess pharmaceutical drugs, if the agent or employee is acting in the usual course of his or her business or employment.

3. The board may permit out-of-state wholesale drug distributors, drug outsourcers, third-party logistics provider, or out-of-state pharmacy distributors to be licensed as required by sections 338.210 to 338.370 on the basis of reciprocity to the extent that the entity both:

   (1) Possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor, pharmacy distributor, drug outsourcers, or third-party logistics provider of this state as prerequisites for obtaining a license under the laws of this state; and

   (2) Distributes into Missouri from a state which would extend reciprocal treatment under its own laws to a wholesale drug distributor, pharmacy distributor, drug outsourcers, or third-party logistics provider of this state.

4. The provisions of subsection 3 of this section shall not apply if a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider is located outside of the United States and licensed in its local jurisdiction under legal standards comparable to those that are to be met by a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider of this state.

   Except if a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider is located outside of the United States and licensed in its local jurisdiction under legal standards comparable to those that are to be met by a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider of this state, it shall be
unlawful for any out-of-state wholesale drug distributor, out-of-state pharmacy acting as a
distributor, drug outsourcers, or third-party logistics provider to do business in this state without
first obtaining a license to do so from the board of pharmacy and paying the required fee, except
as otherwise provided by section 338.335 and this section. Application for an out-of-state
wholesale drug distributor's, drug outsourcer's, or out-of-state third-party logistics provider's
license under this section shall be made on a form furnished by the board. The issuance of a
license under sections 338.330 to 338.370 shall not change or affect tax liability imposed by the
Missouri department of revenue on any entity. Any out-of-state wholesale drug distributor that
is a drug manufacturer and which produces and distributes from a facility which has been
inspected and approved by the Food and Drug Administration, maintains current approval by the
federal Food and Drug Administration, and has provided a copy of the most recent Food and
Drug Administration Establishment Inspection Report to the board, and which is licensed by the
state in which the distribution facility is located, or, if located within a foreign jurisdiction, is
authorized and in good standing to operate as a drug manufacturer within such jurisdiction, need
not be licensed as provided in this section but such out-of-state distributor shall register its
business name and address with the board of pharmacy and pay a filing fee in an amount
established by the board.

338.340. Except if a drug distributor, pharmacy, drug outsourcer, or third-party
logistics provider is located outside of the United States and licensed in its local jurisdiction
under legal standards comparable to those that are to be met by a drug distributor,
pharmacy, drug outsourcer, or third-party logistics provider of this state, no person acting
as principal or agent for any out-of-state wholesale drug distributor, out-of-state pharmacy
distributor, drug outsourcer, or out-of-state third-party logistics provider shall sell or distribute
drugs in this state unless the entity has obtained a license pursuant to the provisions of sections
338.330 to 338.370.
FIRST REGULAR SESSION

HOUSE BILL NO. 727

100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE CLEMENS.

AN ACT

To amend chapter 197, RSMo, by adding thereto one new section relating to multidose medications given to patients at discharge.

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

Section A. Chapter 197, RSMo, is amended by adding thereto one new section, to be known as section 197.180, to read as follows:

197.180. 1. Medications in multidose containers that were administered to or used for a patient during the patient's hospital stay may, if so ordered by an authorized health care provider, be sent with the patient at discharge to the patient's home or to another health care facility.

2. Multidose medications shall include, but are not limited to, inhalers, ointments, creams, medications requiring the original container for dispensing, insulin pens and vials, eye drops, ear drops, wearable or on-body medication delivery systems, and infusions that are currently connected to the patient's infusion device.

3. Multidose medications shall be labeled with the date, patient's name, prescriber's name, name and address of the hospital, medication name and strength, instructions for use, and other pertinent information. Labeling shall be performed by a pharmacist, prescriber, or registered nurse. Labeled instructions for use may refer to specific written instructions provided by a pharmacist, prescriber, or registered nurse at the time of discharge.

4. Controlled substances shall not be sent with the patient, except that wearable or on-body medication delivery systems of controlled substances or controlled substance infusions currently connected to the patient's infusion device may be sent if:

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.
(1) The medication is necessary for administration during transport of the patient;
(2) The quantity of the controlled substance sent is documented in the patient's medical record by the person sending the medication; and
(3) The pharmacy is notified that the medication was sent with the patient.

5. Nothing in this section shall require a class B hospital pharmacy to obtain or comply with additional licensure or regulatory requirements.