The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The meeting was called to order by President Christian Tadrus at approximately 3:02 p.m. on September 13, 2017. Each item in the minutes is listed in the order discussed.

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

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

**Others Present**
Curtis Thompson, General Counsel

PRESIDENT CHRISTIAN TADRUS CALLED THE MEETING TO ORDER AT 8:09 A.M. AND ROLL CALL WAS TAKEN.

**MOTION TO CLOSE 8:10 A.M.**

At 8:10 a.m., Pamela Marshall made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 by roll call vote as follows:

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

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 8:47 a.m.

#A3 Approval of Minutes

A motion was made by Douglas Lang, seconded by Anita Parran, to approve the open session minutes for February 22, 2017. Motion passed 3:0:1:1 by roll call vote as follows:

Barbara Bilek – absent  
Anita Parran – yes  
Douglas Lang- yes  
Pamela Marshall – abstain  
Christina Lindsay – yes

A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the open session minutes for March 15, 2017. Motion passed 3:0:1:1 by roll call vote as follows:

Barbara Bilek – absent  
Anita Parran – yes  
Douglas Lang- yes  
Pamela Marshall – yes  
Christina Lindsay – abstain

A motion was made by Douglas Lang, seconded by Anita Parran, to approve the open session minutes for March 29, 2017. Motion passed 2:0:2:1 by roll call vote as follows:

Barbara Bilek – absent  
Anita Parran – yes  
Douglas Lang- yes  
Pamela Marshall – abstain  
Christina Lindsay – abstain

A motion was made by Douglas Lang, seconded by Anita Parran, to approve the open session minutes for April 7, 2017. Motion passed 4:0:0:1 by roll call vote as follows:

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

A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the open session minutes for April 18 -20, 2017. Douglas Lang asked if inspectors have access to the St. Louis County Prescription Drug Monitoring Program; Kimberly Grinston reported the Memorandum of Understanding with St. Louis County needs to be finalized. Mr. Lang further inquired about allowing multiple business names to be registered by a licensee as previously discussed by the Board. Kimberly Grinston reported the current licensure system can only handle a limited number of d/b/a names. Board discussion held; Board consensus to invite a representative from the Secretary of State’s Office (SOS) to meet with the Board to discuss the current SOS fictitious name/dba registration process and requirements. Curtis Thompson suggested contacting SOS General Counsel Frank Jung. Mr. Lang further noted the Board’s...
sterile compounding review committee still needs to discuss developing a standard sterile compounding questionnaire for new applicants. **Motion passed 4:0:0:1 by roll call vote as follows:**

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

#A4. **Rule Review**

**DISCUSSION:** Kimberly Grinston reported the Governor’s Office has suggested that state agencies consider holding the rule review meetings required by Executive Order 17-03 in different areas of the state. Board discussion held; Christian Tadrus indicated extensive travel may not be possible given the current Executive Order deadlines. Douglas Lang suggested holding a public rule review hearing as part of the Board’s upcoming October meeting in St. Louis. Board discussion held on ways to leverage technology (e.g., a conference call, webcast). Board consensus not to schedule additional meetings at this time but to research the possibility of a webcast or similar remote/electronic meeting. Further Board consensus to hold a public rule review hearing at the October meeting in St. Louis. The following additional Board discussion was held:

- **20 CSR 2220-2.010:** Board discussion held; Board suggestions are included in Attachment A. Board consensus to review changes at a future meeting.
- **20 CSR 2220-2.012:** Board discussion held; Board consensus to review language from other states on temporary absences and the definition of pharmacy permit area at a future meeting.

**MOTION TO CLOSE 11:00 A.M.**

At 11:00 a.m., Christina Lindsay made a motion, seconded by Pamela Marshall, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. **Motion passed 4:0:0:1 by roll call vote as follows:**

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

**RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 12:54 p.m.

#A4. **Rule Review (Cont’d)**

**DISCUSSION:** The Board continued the following discussion:
• **20 CSR 2220-2.090**: No comments received; Board discussion to review at a future meeting along with proposed changes to 20 CSR 2220-2.010 and 20 CSR 2220-2.012 previously discussed.

• **20 CSR 2220-6.040**: Board discussion held; Board suggestions are included in Attachment A. Board consensus to review changes at a future meeting.

• **20 CSR 2220-6.050**: Board discussion held; Board suggestions are included in Attachment A. Board consensus to review changes at a future meeting.

#A5. **General Administration Report**

**DISCUSSION:** Executive Director Kimberly Grinston provided the following updates:

- The Department approved the proposed New Decision Items requested by the Board for the 2018 legislative session. The Department hasn’t issued a final decision on the Board’s proposed continuing education, third-party logistic providers and drug outsourcer legislation. The proposed pharmacy technician legislation was not approved by the Governor’s office; Governor approval of the Board’s other proposed legislation is still pending.

- **Patient Safety Conference:** The Board’s patient safety conference will be held in St. Louis in October 2017. Staff has identified a location in St. Charles but Board members asked to consider a location more centrally located such as the downtown Marriott. Health Literacy Missouri and Steve Calloway with MO HealthNet are scheduled to present. Tom Glenski suggested focusing on patient safety instead of providing a general compliance session that may not be applicable to all attendees.

- The Governor’s Task Force on Board and Commissions has held several meetings in Jefferson City, Missouri. The Task Force did not discuss establishing a conglomerate regulatory Board for all health care providers as previously considered, however, discussion was held regarding consolidation of multiple Bd. of Healing Arts committees. Proposed Task Force recommendations may be issued in October.

- Christian Tadrus reported he is a member of NABP’s task force on defining the pharmacist-patient relationship which recently met. The task force will be considering other state and international models in the future. Board members were asked for suggestions/recommendations. Douglas Lang questioned if further definition is required given the trend towards multi-disciplinary healthcare teams. Christian Tadrus asked Board members to e-mail any suggestions to his attention; Curtis Thompson reminded Board members to copy the Executive Director on any e-mails to ensure Sunshine Law compliance.

- Pamela Marshall reported she recently attended the Missouri Pharmacy Association (MPA) annual meeting which was very informative, including, the presentations on suicide prevention and diabetes training. The Board also provided an informative compliance program.

- The Board received positive feedback on the August newsletter mailed to pharmacist licensees.
• Public Attendee Samuel Leveritt inquired about the status of the previously proposed nuclear pharmacy working group. Kimberly Grinston reported the initial meeting will be held on November 15, 2017.

• Public Attendee Ron Fitzwater with MPA reported the Board’s work on medication safety was mentioned at the Governor’s opioid task force and noted this area provides a strong opportunity for pharmacy involvement. MPA will continue to work with DHSS and other state partners.

MOTION TO CLOSE 1:54 P.M.

At 1:54 p.m., Pamela Marshall made a motion, seconded by Douglas Lang, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

RETURN TO OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 3:23 p.m.

MOTION TO ADJOURN

At approximately 3:23 p.m., a motion was made by Christina Lindsay, seconded by Anita Parran, to adjourn the September 13, 2017, meeting. Motion passed 3:0:0:2 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay –yes

The meeting was adjourned.

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KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved: 2/7/18
20 CSR 2220-2.010 Pharmacy Standards of Operation

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

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

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

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

(C) In addition to a designated pharmacist-in-charge, pharmacy operations must be conducted under the supervision of a pharmacist at all times and comply with 20 CSR 2220-2.012.

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

(2) Equipment. Pharmacies must be equipped with the following:

(A) Properly functioning pharmaceutical equipment for the pharmacy services performed as recognized by the latest edition of the United States Pharmacopoeia (USP) or Remington’s Pharmaceutical Sciences; and

(B) A manual system/device or other equipment for numbering or uniquely identifying prescriptions and medication orders along with appropriate equipment for producing prescription/medication order labels.

(3) Reference Materials. The following references/resources must be physically maintained or immediately accessible in electronic form at the pharmacy:
(A) A current print or electronic edition of statutes and rules governing the pharmacy’s practice, including, but not limited to, Chapters 338 and 195, RSMo, 20 CSR 2220 and, if applicable, 19 CSR 30 governing controlled substances;

(B) Reference(s) or resources(s) that include all drugs approved by the United States Federal Drug Administration (FDA); and

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

1. Pharmacology of drugs;
2. Dosages and clinical effects of drugs; and
3. Patient information and counseling.

(4) General Standards of Operation. All pharmacies licensed by the Board shall comply with all applicable state and federal law governing pharmacy practice and medication handling, disposal and distribution. Except as otherwise provided by law, Board licensed pharmacies must ensure:

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

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

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

(E) Medication and drug-related devices are properly and accurately prepared, packaged, dispensed, distributed and labeled under clean, and when required, aseptic conditions;

(F) The pharmacy is maintained in a clean and sanitary condition and trash is disposed of in a timely manner. Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law;
(G) Appropriate sewage disposal and a hot and cold water supply are available within the pharmacy, except as otherwise provided by the Board. The required water supply may not be located within a bathroom; and

(H) The pharmacy is free from insects, vermin and animals of any kind, except for service animals as defined by the Americans with Disabilities Act (ADA).

(5) Drug Storage. Drugs must be properly stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the FDA approved drug product labeling or the United States Pharmacopeia (USP).

(A) Temperatures in drug storage areas must be recorded and reviewed at least once each day the pharmacy is in operation. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that are reviewed at least once daily.

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

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

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

(E) Appropriate lighting, ventilation and humidity must be maintained in areas where drugs are stored and dispensed.
(6) Security. Adequate security and locking mechanisms must be maintained to prevent unauthorized pharmacy access and to ensure the safety and integrity of drugs and confidential records. Pharmacy traffic must be restricted to authorized persons so that proper control over drugs and confidential records can be maintained at all times.

(A) If the pharmacy is located in a facility that is accessible to the public and the pharmacy’s hours of operation are different from those of the remainder of the facility, ceilings and walls must be constructed of a substantial material so that the pharmacy permit area is separate and distinct from the remainder of the facility. Drop down ceilings or other openings that would allow unauthorized access into the pharmacy are not allowed.

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

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

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

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

1. A separate file for Schedule I and II controlled substances;
2. A separate file for Schedules III, IV and V controlled substances; and
3. A separate file(s) for all other prescriptions/medication orders.
(B) Distribution records. Unless otherwise authorized by law or the Board, pharmacies shall maintain inventories and records of all legend drugs received and distributed that include:

1. Date of the transaction/distribution;
2. Product name, strength and quantity;
3. The names of the parties;
4. The sender’s address or, for drugs distributed by the pharmacy, the receiver’s address; and
5. Any other information required by state or federal law.

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

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

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

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

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

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

(A) The pharmacy’s name and permit number;
(B) Name of person making the notification;

(C) The licensee’s or registrant’s name and license/registration number;

(D) Date of action;

(E) Reason for action; and

(F) Any additional information required by law.

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

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

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

1. Injectable dosage forms of sodium chloride and water;

2. Irrigation dosage forms of sodium chloride and water;

3. Injectable dosage forms of heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;

4. Injectable dosage forms of diphenhydramine, epinephrine and methylprednisolone;

5. Vaccines; and

6. Tuberculin test material.

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

1. Specific drugs authorized to be possessed by the agency and the nurse;

2. Indications for use of the drugs possessed;

3. Receiving orders from an authorized prescriber for drug administration;

4. Leaving drugs with the patient for routine care procedures;

5. Conditions for storing and transporting drugs by the agency and nurse; and

6. Quantity of drugs possessed by the agency and nurse.

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

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

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

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

(13) Exemptions. At its discretion, the Board may grant an exemption to the facility requirements of this rule if such exemption is not contrary to law and the exemption will provide equal or greater protection of the public safety, health or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length and proposed procedures or safeguards for protecting the public safety, health or welfare if the exemption is approved.

PURPOSE: This rule establishes supervision requirements for Missouri licensed pharmacies.

(1) Definitions.

(A) “Pharmacy Permit Area” - An area within the same physical address of a pharmacy that has been inspected and approved by the Board as part of the pharmacy permit.

(B) “Practice of Pharmacy” - Any activity within the practice of pharmacy as defined by Chapter 338, RSMO.

(2) Except as otherwise provided in section (3) of this rule or by other applicable law, no prescription or medication order may be prepared, compounded, dispensed, handled or otherwise provided without a pharmacist on duty who is present within the pharmacy permit area and able to render immediate assistance and correct errors.

(A) Pharmacies must maintain current and accurate policies and procedures governing pharmacy technician and intern pharmacist allowed activities and standards for supervision. Policies and procedures may be manually or electronically maintained at the pharmacy, provided they are available at the request of the Board or the Board’s authorized designee.

(B) During pharmacy business hours, a sign with a minimum of two inch (2”) lettering must be prominently displayed in an area that is easily viewable to the public advising the public when no pharmacist is on duty.

(C) Except as otherwise provided by law, a pharmacist must verify the accuracy of:

1. Prescription or medication order data on each original prescription or medication order prior to dispensing; and

2. The final contents and affixed label of each new and refill prescription or medication order prior to dispensing.

(3) Authorized Activities During a Pharmacist’s Temporary Absence. Except as otherwise authorized by law, intern pharmacists and pharmacy technicians may perform the following activities when a pharmacist is absent:

(A) Pharmacist On Premises. Interns and pharmacy technicians may continue to assist in the practice of pharmacy when a pharmacist is temporarily absent from the pharmacy permit area.
provided the pharmacist is physically present on the pharmacy’s premises [at the pharmacy’s location] and able to provide assistance in the event of an emergency. If authorized by the pharmacist-in-charge, complete and labeled prescriptions or medication orders that have been verified by a pharmacist may be dispensed during a temporary absence. If pharmacist counseling is requested, the medication may not be dispensed until the pharmacist is present or, at the patient’s option, a contact number for the patient may be collected for the pharmacist to call on return. If the temporary absence exceeds thirty (30) minutes, the no pharmacist on duty sign must be posted and no further dispensing or pharmacy activities may take place except as otherwise authorized by subsection (3)(B) of this rule.

(B) Pharmacist Not On Premises. If authorized by a pharmacist or the permit holder, intern pharmacists and pharmacy technicians may perform the following activities when a pharmacist is not physically present on the pharmacy premises [at the pharmacy location]:

a. Receive medication deliveries, however, the medication may not be stocked or otherwise handled, and;

b. Accept written, faxed or electronic prescriptions, medication orders and refill requests, provided the prescription, medication order or refill request may not be prepared, compounded, filled or dispensed.

(C) Notwithstanding any provision of this rule, no compounding may be performed without a pharmacist present within the pharmacy permit area and supervising.
20 CSR 2220-2.090 Pharmacist-in-Charge

PURPOSE: This amendment updates and further defines the duties of the pharmacist-in-charge.

(1) Except as otherwise authorized by law, each pharmacy shall designate a pharmacist-in-charge who is responsible for managing pharmacy compliance and supervising pharmacy staff. At a minimum, the pharmacist-in-charge shall ensure pharmacy operations comply with the rules of the Board and all applicable state and federal law governing pharmacy practice, including, but not limited to, 20 CSR 2220-2.010 and all applicable controlled substance laws.

(2) A pharmacist must immediately notify the Board electronically or in writing on a form designated by the Board if he/she stops serving as the designated pharmacist-in-charge. At or immediately prior to a pharmacist-in-charge change, a controlled substance inventory must be taken by a designee of the permit holder that complies with state and federal biennial controlled substance inventory requirements, including, 21 CFR § 1304.11. The signature of the individual(s) taking the required inventory must be documented on the inventory.

(3) This rule shall not be construed to exempt a permit holder from responsibility for compliance with applicable state or federal law.


20 CSR 2220-6.040 Administration by Medical Prescription Order

PURPOSE: This rule establishes procedures for pharmacists to administer medication pursuant to a medical prescription order.

1. A pharmacist who complies with the provisions of this rule may administer drugs and devices pursuant to a medical prescription order, including, vaccines.

2. Except as otherwise provided by law, a pharmacist may not delegate medication administration to another person, except to an intern pharmacist who has met the qualifications of subsections (3)(B) – (E) and is working under the direct supervision of a pharmacist who has met the qualifications to administer drugs by medical prescription order. Intern pharmacists must maintain proof of compliance with subsections (3)(B) – (E) for a minimum of two (2) years.

3. Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the Board. To file a Notification of Intent, a pharmacist must—
   A. Hold a current Missouri pharmacist license;
   B. Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) certification or Basic Life Support certification issued by the American Heart Association, the American Red Cross or an equivalent organization. The certificate program must have included a live training component [in-person skills assessment];
   C. Have successfully completed a certificate program in medication administration and emergency procedures accredited by the Accreditation Council for Pharmacy Education (ACPE) or provided by a governmental entity or a healthcare professional organization or educational institution approved by the Board. To obtain Board approval, the training program must provide instruction in:
      1. Administration techniques, including, hands-on training in routes of administration;
      2. Drug storage and handling;
      3. Informed consent requirements;
      4. Pre- and post- administration assessment and counseling;
      5. Biohazard waste disposal, and;
      6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks.
   D. If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist must first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of the required training and training date(s) must be maintained at the pharmacy and available to the Board on request.
(E) Proof of compliance with this section must be maintained for a minimum of two (2) years.

(4) General Requirements.

(A) Medication must be administered in compliance with all applicable state and federal law, including applicable Vaccine Information Statements and informed consent requirements. Except as otherwise authorized by law, vaccines must also be administered in accordance with current treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer’s guidelines.

(B) Pharmacists must have a current and accurate written policy and procedure manual covering all aspects of administering drugs by medical prescription order, including:

1. Drug administration procedures;
2. Authorized routes of administration;
3. Drug storage;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal and disposal of used/contaminated supplies;
6. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
7. Recordkeeping and notification procedures and requirements.

(C) Drugs must be stored within the manufacturer’s labeled requirements, including when administering outside of a pharmacy. Vaccines must be stored in accordance with CDC guidelines at all times.

(D) Patients must be asked to remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

(5) Requirements of Medical Prescription Order. At a minimum, the medical prescription order from a licensed prescriber must include:

(A) The name of the licensed prescriber issuing or authorizing the order;
(B) The name of the patient to receive the drug;
(C) The name of the drug and dose to be administered;
(D) The route of administration;
(E) The date of the original order; and
(F) The date or schedule, if any, of each subsequent administration.

(6) Record Keeping.

(A) Pharmacists administering or supervising administration of medication pursuant to this rule shall ensure the following records are manually or electronically maintained separate from the prescription files of a pharmacy for each administration:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The medication name and dose. For vaccines and biologics, the manufacturer, expiration date and lot number must also be documented and recorded;
4. For vaccines, the name and address of the patient’s primary health care provider, as identified by the patient or an indication that a primary health care provider was not provided;
5. The identity of the administering pharmacist or, if applicable, the administering intern pharmacist and his/her supervising pharmacist;
6. If applicable, the nature of an adverse reaction and who was notified; and
7. Documentation of a patient’s refusal or failure to remain in or return to the pharmacy after administering a vaccine to observe any adverse reactions.

(B) All records required by this rule must be kept by the pharmacist for two (2) years from the date of such record. Except as otherwise required by section (3), records must be kept at the pharmacy where the prescription order is maintained or may be securely stored offsite at a location designated by the pharmacist. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the Board or the Board’s authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a Board request.

(7) Notification Requirements. Pharmacists administering or supervising administration of medication under this rule, shall ensure:

(A) The patient’s primary health care provider is notified of the following within fourteen (14) days of administering a vaccine:
1. The identity of the patient;
2. The vaccine administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration;

(B) The prescriber is notified within twenty-four (24) hours after learning of an adverse event or reaction experienced by a patient following administration. Notification is mandatory and cannot be waived;

(C) Administered vaccines are reported to the Missouri immunization registry operated by the Missouri Department of Health and Senior Services (ShowMeVax), or its successor; and

(D) Any notifications required by state and federal law are properly completed and documented.

(E) Notifications required by this subsection may be made electronically or in writing or via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Documentation of the required notifications,
including the notification date, must be maintained as required by section (6)(B) or
electronically retrievable at the request of the Board or the Board’s authorized designee.

(8) Notification of Intent Refiling. To continue administration, a Notification of Intent to
administer drugs by medical prescription order must be refiled with the Board biennially
along with the pharmacist’s Missouri pharmacist license. To refile, a pharmacist must
hold a current health care provider Basic Life Support certification issued by the
American Heart Association, the American Red Cross or an equivalent organization.
The certification program must have included a live training component.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and section 338.010.1,

RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971,
1981.
PURPOSE: This rule establishes the procedures for pharmacists to administer vaccines per written protocol with a physician.

(1) General Requirements. A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol with a Missouri licensed physician who is actively engaged in the practice of medicine. Unless otherwise restricted by the governing protocol, vaccines may be administered at any Missouri licensed pharmacy or any non-pharmacy location identified in the governing protocol.

(A) Vaccines must be administered in accordance with current treatment guidelines established by the Centers for Disease Control (CDC) and the manufacturer’s guidelines, provided CDC guidelines shall control in the event of a conflict. Vaccines may not be administered to individuals under twelve (12) years old unless otherwise authorized by law.

(B) Pharmacists shall ensure compliance with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) Vaccines must be stored in accordance with CDC guidelines/recommendations and within the manufacturer’s labeled requirements, including, when vaccinating outside of a pharmacy.

(D) A pharmacist may only delegate vaccine administration to an intern pharmacist who has met the qualifications of subsections (3)(B) and (C) of this rule and is working under the direct supervision of a pharmacist qualified to administer vaccines. Proof of an intern’s compliance with subsections (3)(B) and (C) must be maintained by both the supervising pharmacist and the intern pharmacist for a minimum of two (2) years.

(2) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.

(3) Pharmacist Qualifications. Pharmacists administering vaccines by protocol as authorized by Chapter 338, RSMo, must first file a Notification of Intent (NOI) to administer vaccines with the Missouri Board of Pharmacy. To file a NOI, a pharmacist must-

(A) Hold a current Missouri pharmacist license;

(B) Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification issued by the American Heart Association, the American Red Cross
or an equivalent organization. The qualifying BLS or CPR certification program must have
included a live in-person skills assessment; and

(C) Have successfully completed a certificate program in administering vaccines accredited by
the Accreditation Council for Pharmacy Education (ACPE) or provided by a governmental
entity, healthcare professional organization or educational institution approved by the Board of
Pharmacy. To be approved, non-ACPE programs must include a live/in-person training
component and include instruction in:

1. Current CDC guidelines and recommendations for vaccines authorized by Chapter
   338, RSMo, including, recommended immunization schedules;
2. Basic immunology and vaccine protection;
3. Physiology and techniques for vaccine administration, including, hands-on training in
   intramuscular, intradermal, subcutaneous and nasal administration routes and other
   common routes of vaccine administration;
4. Pre- and post- vaccine screening or assessment; and
5. Identifying and treating adverse immunization reactions.

(D) Notifications of Intent must be filed on the Board’s website or on a form approved by the
Board.

(4) Protocol Requirements.

(A) In addition to filing a NOI, pharmacists administering vaccines under this rule must first
enter into a written protocol with a Missouri licensed physician. The written protocol may be
valid for a time period not to exceed one (1) year. The protocol must be renewed annually and
include the following:

1. The identity of the participating pharmacist and physician;
2. Time period of the protocol;
3. Authorized vaccines;
4. The patient or groups of patients authorized for vaccination;
5. Allowed routes and anatomic sites of administration;
6. If applicable, authorization to create a prescription for each administration under the
   physician’s name;
7. Emergency response procedures, including, but not limited to, procedures for
   handling/addressing adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. The length of time the pharmacist must observe an individual for adverse events following an injection;
9. Procedures for disposing of used and contaminated supplies;
10. The street addresses of any non-pharmacy locations at which the pharmacist may administer vaccines;
11. Record-keeping requirements and any required notification procedures; and
12. A provision allowing termination of the protocol at any time at the request of any party.

(B) The protocol, and any subsequent amendments or alterations, must be reviewed and manually or electronically signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its contents and agree to follow the terms of the protocol. A copy of the protocol must be maintained by both the pharmacist and the authorizing physician for a minimum of eight (8) years after termination of the protocol.

(C) Additional pharmacists or immunization locations may be added to an existing protocol if the amendment is signed and dated by the authorizing physician(s) and, if applicable, any newly added pharmacist(s). Existing pharmacists are not required to re-sign the protocol unless other protocol terms or provisions are changed.

(5) Record Keeping.

(A) The pharmacist shall ensure a record is maintained for each vaccine administered by protocol that includes:

1. The patient’s name, address, and date of birth;
2. The date, route, and anatomic site of administration;
3. The vaccine’s name, dose, manufacturer, lot number, and expiration date;
4. The name and address of the patient’s primary health care provider, if provided by the patient;
5. The identity of the administering pharmacist or intern pharmacist; and
6. The nature of any adverse reaction and who was notified, if applicable.

(B) Within seventy-two hours (72) hours after a vaccine is administered, a prescription must be obtained from the authorizing physician for the drug dispensed or a prescription must be created in the physician’s name documenting the dispensing as authorized by protocol. Notwithstanding any other provision of this rule, prescription records must be maintained as provided by Chapter 338, RSMo, and the rules of the board.
(D) The records required by this rule must be securely and confidentially maintained as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure the records required by subsection (5)(A) are promptly delivered to and maintained at the pharmacy separate from the pharmacy’s prescription files;

2. If the vaccine is not administered on behalf of a pharmacy, records must be maintained by the administering or supervising pharmacist at an address identified in the protocol prior to administering the vaccine; and

3. Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the board.

(C) Records required by this rule must be maintained for two (2) years and made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the State Board of Pharmacy and/or their authorized representatives. Records not maintained at a pharmacy must be produced within three (3) business days of a request from the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives.

(6) Notification of Immunizations. All pharmacists provided immunizations must be reported to the Missouri immunization registry operated by the Missouri Department of Health and Senior Services (ShowMeVax). Additionally, pharmacists must:

(A) Notify all persons or entities as required by state and federal law;

(B) Notify the protocol physician as required by the governing protocol;

(C) Notify the patient’s primary care provider as required by Chapter 338, RSMo; and

(D) Notify the patient’s primary health care provider and, if different, the protocol physician, within twenty-four (24) hours after learning of any adverse event or reaction experienced by the patient. Adverse events or reactions must also be reported to the Vaccine Adverse Event Reporting System (VAERS) or its successor, within thirty (30) days.

(E) Unless otherwise provided by the governing protocol, notification may be made via a common electronic medication record that is accessible to and shared by both the physician and
pharmacist. Proof of notification must be maintained in the pharmacist’s records as provided in section (5)(C) of this rule.

(7) Notification of Intent Renewal. A Notification of Intent (NOI) to immunize by protocol must be renewed biennially with the immunizing pharmacist’s Missouri pharmacist license. To renew a NOI, pharmacists must:

(A) Have a current Missouri pharmacist license;

(B) Have a current healthcare provider cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification that complies with section (3)(B) of this rule; and

(C) Have completed a minimum of two (2) hours of continuing education (0.2 CEU) related to administering vaccines or CDC immunization guidelines in a course provided by the Board or an ACPE accredited continuing education provider within the applicable pharmacist biennial renewal period (November 1st to October 31st of the immediately preceding even numbered years). Alternatively, continuing education may be provided by a governmental entity, healthcare professional organization or educational institution approved by the Board in advance. Approval requests for non-ACPE programs must be submitted in accordance with 20 CSR 2220-7.080. To be approved, non-ACPE programs must provide instruction in one or more of the following:

1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including, recommended immunization schedules;

2. Basic immunology and vaccine protection;

3. Physiology and techniques for vaccine administration;

4. Pre- and post- vaccine screening or assessment; or

5. Identifying and treating adverse immunization reactions.

(D) The required continuing education (CE) shall be governed by 20 CSR 2220-7.080 and may be used to satisfy the pharmacist’s biennial continuing education requirements. The initial training program required by subsection (3) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within the applicable pharmacist biennial renewal cycle.