Notice is hereby given that the Missouri Board of Pharmacy will be meeting on February 7, 2018. If any member of the public wishes to attend the meeting, s/he should be present at the Adams Pointe Conference Center & Courtyard by Marriott; 1400 NE Coronado Dr.; Blue Springs, MO at 8:00 a.m. on February 7, 2018.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes, to the extent they relate to the following: Sections 610.021(1), (3), (5), (6), (7), (13), (14), and (17), RSMo, and Section 324.001.8 and .9, RSMo.

The Board may go into closed session at any time during the meeting. 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) 751-0093 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.
February 7, 2018

Note: The following items will be discussed as time allows. Except as noted below, items may be discussed in any order. Additionally, the Board may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

#A1. Call to Order Christian Tadrus, PharmD, President (8:00 a.m.)

#A2. Roll Call

***The Board will go immediately into closed session and will reconvene in open session at approximately 8:30 a.m. on February 7, 2018***

#A3. Agenda Additions/Corrections

#A4. Approval of Minutes
   - September 13, 2107
   - July 25, 2017
   - October 25, 2017

#A5. Draft Rule Amendments
   (Draft revisions of the following rules are currently under review)
   - 20 CSR 2220-2.010 Pharmacy Standards of Operation
   - 20 CSR 2220-2.012 Pharmacy Supervision
   - 20 CSR 2220-2.090 Pharmacist-In-Charge
   - 20 CSR 2220-2.130 Drug Repackaging
   - 20 CSR 2220-2.190 Patient Counseling

#A6. 2018 Practice Guide Revision
   - Draft 2018 Practice Guide

#A7. Red Tape Reduction Report/Rule Amendments

#A8. Staff/Board Member Meetings Report
   - Nuclear Sub-Committee/Updates on revised 20 CSR 2220-2.500
   - DMH/NPA Naloxone Training
   - Dept. of Health Immunization Training
A9. General Administration Report
   - Staff/Office Update
   - Financial Report/Technician Renewal Fee
   - 2018 Legislation and Budget Requests
   - Rule Update (Pending and Red Tape Rule Review)
   - Bd. of Healing Arts Review of 20 CSR 2220-6.050
   - NABP Annual Meeting (May 5-8 2018 – Denver, Colorado)

A10. Implementation of SB 501/Rx Cares for Missouri Program


A12. Fiscal Year 2018-2019 Strategic Plan
   - 2017 Strategic Plan Draft
   - California Board of Pharmacy Strategic Plan

A13. 20 CSR 2220-2.200/Remediation Activities After A Positive Test/Sample
   - The Board has been asked to reconsider 20 CSR 2220-2.200(20)’s requirement that pharmacies terminate compounding if a positive test identified in subsection (20) is discovered if a highly pathogenic microorganism is detected.

A14. Applications for Intern Training Special Site/Non-Pharmacist Preceptor
   - Cerner Corp.
   - CVS Pharmacy Business Office
   - Kansas City VA Medical Center- Honor Annex
   - Kansas City VA Medical Center- Shawnee Community Based Outpatient Clinic
   - Ranken Jordan
   - Southern Illinois Healthcare
   - SSM Select Rehabilitation Hospital
   - St. Louis College of Pharmacy
   - Trinity College (Ireland)
   - Iowa Pharmacy Assoc.

A15. University of Missouri-Kansas City School of Pharmacy-Report-Foreign Intern Training Sites/Special Sites

A16. The Board may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (5), (7), and (14) and under Section 324.001.8, and .9 RSMo. The Board will return to open session at the conclusion of discussion of closed session items.

A17. Adjournment
#A3. Agenda Additions/Corrections
#A4. Approval of Minutes
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:

Anita Parran – yes     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:

Anita Parran – 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:

Anita Parran – yes     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:

Anita Parran – 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:

   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:

   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:

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 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:

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

The meeting was adjourned.

__________________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
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.
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.

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.

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.

Comment [GK3]: Does the Board want to keep the exemption language?
AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and sections 338.010 and
338.210, RSMo Supp. 2007.* This rule originally filed as 4 CSR 220-2.010. Original rule filed
Jan. 10, 1976. Amended: Filed May 21, 1979, effective Nov. 12, 1979. Amended: Filed April 14,
Filed Nov. 4, 1985, effective March 13, 1986. Amended: Filed Dec. 15, 1987, effective April 28,

20 CSR 2220-2.012 Pharmacy Supervision

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.
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,

Comment [GK2]: To register with/use ShowMeVax licensees would need: (1) high speed internet access and (2) access to Internet Explorer (ShowMeVax will not work with any other platform). Users who do not have an electronic system that can automatically report to DHSS have to complete 2 online trainings; all other entities must have a MOU with DHSS including entities reporting for multiple locations. DHSS does not accept paper submissions due to staffing. Does the Bd. still want to require ShowMeVax reporting?
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.
20 CSR 2220-6.050 Administration of Vaccines Per Protocol

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.
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.

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.
E-MAIL BALLOT

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

#C1 Applications for Intern Training Pharmacy Special Site—The Board reviewed:

- **Center Pointe Hospital**
  
  Votes:  
  \- Christina Lindsay—Approved
  \- Christian Tadrus—Approved
  \- Barbara Bilek—Approved
  \- Douglas R. Lang—Approved
  \- Pamela Marshall—Approved
  \- Anita Parran—Approved

- **Ewha Woman’s University, School of Medicine**
  
  Votes:  
  \- Christina Lindsay—Approved
  \- Christian Tadrus—Approved
  \- Barbara Bilek—Hold for Board Discussion
  \- Douglas R. Lang—Approved
  \- Pamela Marshall—Approved
  \- Anita Parran—Approved

- **Kansas City VA Medical Center- Belton Community Based Outpatient Clinic**
  
  Votes:  
  \- Christina Lindsay—Approved
  \- Christian Tadrus—Approved
  \- Barbara Bilek—Approved
  \- Douglas R. Lang—Approved
  \- Pamela Marshall—Approved
  \- Anita Parran—Approved
• Kansas City VA Medical Center

Votes: Christina Lindsay—Approved
Christian Tadrus—Approved
Barbara Bilek—Approved
Douglas R. Lang—Approved
Pamela Marshall—Approved
Anita Parran—Approved

• Kansas City VA Medical Center- Warrensburg Community Based Outpatient Clinic

Votes: Christina Lindsay—Approved
Christian Tadrus—Approved
Barbara Bilek—Approved
Douglas R. Lang—Approved
Pamela Marshall—Approved
Anita Parran—Approved

• Trinity College Dublin, The School of Pharmacy and Pharmaceutical Sciences

Votes: Christina Lindsay—Approved
Christian Tadrus—Approved
Barbara Bilek—Hold for Board Discussion
Douglas R. Lang—Approved
Pamela Marshall—Approved
Anita Parran—Approved

The Board voted to hold Ewha Woman’s University, School of Medicine and Trinity College Dublin, The School of Pharmacy and Pharmaceutical Sciences for Board discussion.

The Board voted to approve Center Pointe Hospital, Kansas City VA Medical Center- Belton Community Based Outpatient Clinic, Kansas City VA Medical Center, Kansas City VA Medical Center- Warrensburg Community Based Outpatient Clinic for 500 hours

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Approved:
The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christian Tadrus at approximately 8:01 a.m. on October 25, 2017. Each item in the minutes is listed in the order discussed.

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

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Bennie Dean, R.Ph., Inspector
Katie DeBold, PharmD, Inspector
Sarah Decker, Compliance Coordinator
Jennifer Luebbert, Administrative Coordinator
Andi Miller, PharmD, Inspector
Scott Spencer, R.Ph., Inspector
Lisa Thompson, R.Ph., Inspector
Dan Vandersand, R.Ph., Inspector
Elaina Wolzak, R.Ph., Inspector
Barbara Wood, R.Ph., Inspector

**Others Present**
Curtis Thompson, Legal Counsel

**PRESIDENT CHRISTIAN TADRUS CALLED THE MEETING TO ORDER AT 8:01 A.M. AND ROLL CALL WAS TAKEN.**

**MOTION TO CLOSE 8:01 A.M.**
At 8:01 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),
Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes            Christina Lindsay – yes

PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 8:01 A.M.

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on October 25, 2017, at approximately 8:43 A.M.

#A3. Agenda Additions/Corrections
No open session additions/corrections identified.

#A4. Executive Order 17-03 Public Rule Hearing

DISCUSSION: President Tadrus opened the hearing pursuant to Executive Order 17-03 and asked for public comments. The following public comments were received:

• Adam Chessler (Cardinal Health) questioned if the proposed Class-J Shared Services rule would allow pharmacists to remotely verify prescriptions for a pharmacy in another facility. Mr. Glenski indicated the proposed rule revision would not allow the activity described; Kimberly Grinston noted remote verification may be relevant to 20 CSR 2220-2.010 which is in the agenda for discussion later in the meeting.

President Tadrus thanked the public for their participation; A full transcript of the public rule hearing is available in the Board’s office.

#A5. 2020 Rule Review

• 20 CSR 2220-2.013 (Prescription Delivery Requirements)
• 20 CSR 2220-2.110 (PRN Refills)
• 20 CSR 2220-2.120 (Transfer of Prescription Information for the Purpose of Refill)
• 20 CSR 2220-2.130 (Drug Repackaging)
• 20 CSR 2220-2.800 (Vacuum Tube Drug Delivery System)
• 20 CSR 2220-2.950 (Automated Filling Systems)
• 20 CSR 2220-2.190 (Patient Counseling)

DISCUSSION: Except as reflected below for 20 CSR 2220-2.190, no public comments were provided on the included rules. The following action was taken by the Board:

• 20 CSR 2220-2.013 (Prescription Delivery Requirements): Board consensus not to modify at this time.
• 20 CSR 2220-2.110 (PRN Refills): Tom Glenski noted the rule was primarily intended to establish that a prescription is not valid after a year. Christian Tadrus
suggested the rule may need to be revisited given the payor industry is beginning to focus on the quantity remaining instead of the number of fills. Douglas Lang questioned if the rule should address expiration dates for controlled substance prescriptions. Board consensus to open the rule for revision; Kimberly Grinston asked Board members to e-mail suggestions to her attention.

- **20 CSR 2220-2.120 (Transfer of Prescription Information for the Purpose of Refill):** Douglas Lang suggested the rule may need to reference DEA guidance on transferring original or electronic prescriptions. Tom Glenski suggested the rule also address mass prescription transfers. Board consensus to open the rule for revision.

- **20 CSR 2220-2.130 (Drug Repackaging):** Douglas Lang suggested the Board review recent FDA guidance on this topic. Board consensus to open the rule for revision.

- **20 CSR 2220-2.800 (Vacuum Tube Drug Delivery System):** Christian Tadrus asked if the rule accommodates current technology. Tom Glenski inspectors are not currently seeing significant compliance issues under the rule. Board discussion held; Board consensus not to revise at this time.

- **20 CSR 2220-2.950 (Automated Filling Systems):** Tom Glenski reported licensees confuse this rule with 20 CSR 2220-2.900. Board discussion held; Board consensus not to revise the rule at this time but to provide further licensee education.

- **20 CSR 2220-2.190 (Patient Counseling):** Public attendee Adam Chessler asked the Board to consider allowing remote patient counseling. Board discussion held; Board consensus to open the rule for revision. Staff asked to research patient counseling language from other states.

A full transcript of the 2020 rule review discussion is available in the Board’s offices.

### Draft Rules Under Review

- **20 CSR 2220-2.010 Pharmacy Standards of Operation**
- **20 CSR 2220-2.012 Pharmacy Supervision**
- **20 CSR 2220-2.085 Electronic Prescriptions and Medication Orders**
- **20 CSR 2220-2.090 Pharmacist-In-Charge**
- **20 CSR 2220-6.040 Administration by Medical Prescription Order**
- **20 CSR 2220-6.050 Administration of Vaccines Per Protocol**

### DISCUSSION:

- **20 CSR 2220-2.010 (Pharmacy Standards of Operation):** Public Attendee Nathan Hanson asked if primary source verification could serve as proof of licensure. Douglas Lang recommended the rule require humidity monitoring and suggested a standard humidity range of 50% - 60%. Barbara Bilek noted federal requirements reference 50% - 60% humidity. Douglas Lang further suggested defining what constitutes “adequate” pharmacy security. Board consensus to research other state humidity requirements.

- **20 CSR 2220-2.012 (Pharmacy Supervision):** Public Attendee Tomson George with Walgreens Pharmacy asked the Board to consider allowing remote supervision of
technician activities. Adam Chessler (Cardinal Health) and Nathan Hanson (Truman Medical Center) also spoke in favor of allowing remote supervision/remote technician activities. Mr. Chessler noted 22 states allow some form of remote technician supervision; Mr. Hanson reported the Department of Defense and the Veterans Administration also has strong remote supervision programs. Board discussion held; Board consensus to define supervision in the draft rules. Christian Tadrus proposed establishing a Board sub-committee to assist in formulating language; Board consensus to establish a sub-committee to develop language addressing technician supervision and allowed activities during a pharmacist’s temporary absence. Pamela Marshall and Christina Lindsay volunteered to serve as sub-committee members.

- 20 CSR 2220-2.090 (Pharmacist-In-Charge): Board discussion held; Board consensus to have the rule sub-committee review language for defining the pharmacy permit area. Douglas Lang also suggested the rule clearly provide that policies and procedures must be accessible to pharmacy personnel. Board consensus to revise as suggested and review at a future meeting.

- 20 CSR 2220-2.085 (Electronic Prescriptions and Medication Orders): Douglas Lang suggested the rule state that controlled substance prescriptions must be signed as required by state and federal law. **A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the proposed rule for filing with the Missouri Secretary of State’s Office with the additional requirement that controlled substance prescriptions must be signed as required by state and federal law. 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

- 20 CSR 2220-6.040 (Administration by Medical Prescription Order) and 20 CSR 2220-6.050 (Immunization by Protocol): Board discussion held regarding allowing ShowMeVax reporting; Board members questioned if the Board could legally allow ShowMeVax reporting as a form of notification. Board consensus to hold pending additional discussion with legal counsel.

**DISCUSSION:** No public comments received; **A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the final order of rulemaking for filing with the Missouri Secretary of State’s Office. 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
#A8. Board Member Reports

- NABP Task Force on Defining The Pharmacist-Patient Relationship
- Missouri Pharmacy Association Annual Meeting
- FDA Inter-Governmental Working Meeting on Pharmacy Compounding
- NABP District 6, 7 & 8 Meeting
- Bd. of Pharmacy 2017 Patient Safety Conference

**DISCUSSION:** The following Board member reports were provided:

- Christian Tadrus recently attended an NABP task force meeting in Chicago, Illinois, regarding defining the pharmacist-patient relationship. Several state representatives attended; Representatives from Canada and the national medical boards also attended. Task force recommendations should be issued by December 2017.

- Pamela Marshall attended the joint Missouri and Illinois Pharmacist Association meeting in St. Louis. Presentations were informative; Executive Director Grinston provided a Board update.

- Mr. Lang attended the FDA Inter-Governmental Working Meeting with Kimberly Grinston in Maryland. The FDA provided updates on their compounding regulatory goals. Multiple state breakout sessions were held to discuss regulatory issues/suggestions. Mr. Lang reported the meeting was informative overall.

- Mr. Tadrus attended the District 6, 7 and 8 meeting in San Antonio, Texas, along with Douglas Lang and Mrs. Grinston. Informative presentations were given on naloxone, opioid education, prescription drug monitoring programs and FDA compounding issues.

- Pamela Marshall and Anita Parran attended the Board’s 2017 Patient Safety Conference in St. Charles. Presentations were provided on patient literacy, naloxone dispensing and the opioid crisis. Approximately 92 people attended. Mrs. Grinston reported final costs were less than $4,000 which was under budget.

- Mrs. Grinston participated in a “Meeting of the Minds” program hosted by St. Louis College of Pharmacy that focused on prescription drug monitoring programs and related regulatory issues. MPA and other legislative lobbyists also participated.

#A9. Approval of Minutes

- May 17, 2017
- June 23, 2017

A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the open session minutes for May 17, 2017. Motion passed 3:0:1:1 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – abstain

A motion was made by Pamela Marshall, seconded by Anita Parran, to approve the open session minutes for June 23, 2017. Motion passed 4:0:0:1 by roll call vote as follows:

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#A10. General Administration Report

- Staff/Office Update
- Financial Report
- 2018 Renewal Fee Decrease
- Governor’s Board and Commissions Task Force
- “Red-Tape” Reduction Initiative
- Bd. of Healing Arts Opioid Safety Conference
- 2018 Proposed Legislation/New Decision Items
- Upcoming Webinars
- Revised Pharmacy Practice Guide
- Pending Rules

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

- Scott Spencer will replace Joe Dino as the Mid-Missouri inspector. Board members welcomed Scott to the Board. Mrs. Grinston also introduced Sarah Decker, the newly appointed Compliance Coordinator.
- Pharmacy and drug distributor renewals will end on October 31st; the renewal period has gone well with few complications.
- The Inspector December training meeting will be held on December 19th; board members are welcome to attend.
- The Board’s fund is strong; Revenue continues to increase. Mrs. Grinston asked the Board to consider a technician renewal fee decrease. The Board reviewed budget scenarios provided by the Division’s budget director; Board discussion held. A **motion was made by Christina Lindsay, seconded by Pamela Marshall, to decrease the technician renewal fee to twenty dollars ($20).** Motion passed 4:0:0:1 by roll call vote as follows:

  Anita Parran – yes        Christina Lindsay – yes

- The Governor’s office has asked the agencies to submit performance measures for budgeting purposes with both a base and target/stretch goal. Mrs. Grinston has been appointed to a Committee to attempt to identify standard goals that could be used by all PR boards. Mrs. Grinston reported the Board does not have strong data, however, she is attempting to identify performance measures the Board can reasonably accomplish given current resources.

**MOTION TO CLOSE 12:12 P.M.**

At approximately 12:12 p.m., Pamela Marshall made a motion, seconded by Christina Lindsay, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1) and (14), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 by roll call vote as follows:  

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#A10. General Administration Report (Cont’d)

- Missouri Hospital Association Opioid Conference

**DISCUSSION:** The following additional information was provided by Mrs. Grinston:

- Kimberly Grinston reported positive feedback was received on the August newsletter mailed to licensees. Board discussion held; Board consensus to also mail the November newsletter.

- Kimberly Grinston reported MHA asked the Board to financially co-sponsor a statewide opioid conference along with the other Division health boards. Mrs. Grinston reported the Board cannot co-sponsor a private entity conference but could assist as a partner. Mrs. Grinston indicated the requested financial assistance is currently unknown given MHA is in the preliminary planning stages. Mrs. Grinston noted MHA proposed an attendance fee of $75 - $100. Board discussion held; Board members expressed concerns with limited pharmacy program content. Board consensus not to sponsor the opioid conference at this time but to allow pharmacist continuing education credits if an application is submitted.

- Ron Fitzwater with the Missouri Pharmacy Association (MPA) asked if the Board would be interested in publishing information in MPA’s newsletter; Board members expressed interest. Board consensus to submit an article for future publication by MPA.

- Mrs. Grinston has communicated with the Missouri Department of Health and Senior Services (DHSS) on ideas for implementing the Rx Cares for Missouri program; DHSS has advised they would be interested in direction from the Board. Board discussion held on implementing the program. Board consensus to review the suggestions submitted to the Governor’s office when the Rx Cares for Missouri language was originally drafted by the Board. Board consensus to discuss at a future meeting.

- Mrs. Grinston reported DHSS has indicated a statutory change would be required to implement the drug take back program approved by SB 501. Additional information will be provided once received.

- Board members were asked if the Board wanted to revise the Pharmacy Practice Guide at this time given several rule amendments have been approved/filed. Board consensus to begin revisions but note in the Practice Guide that rule changes are pending.

#A6. Draft Rules Under Review (Cont’d)

- 20 CSR 2220-6.040 Administration by Medical Prescription Order
- 20 CSR 2220-6.050 Administration of Vaccines Per Protocol

**DISCUSSION:** After consultation with legal counsel, the following Board discussion was held:
20 CSR 2220-6.040 & 20 CSR 2220-6.050: Board discussion held; A motion was made by Douglas Lang, seconded by Christina Lindsay, to approve the proposed rule for filing with the Missouri Secretary of State’s Office. Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes       Christina Lindsay – yes

Final approved rule language is included in Attachment A.

#A12. USP Chapter 800 & 797 Updates
- Staff Updates

DISCUSSION: Mrs. Grinston reported USP has delayed implementation of Chapter 800 to coincide with the anticipated USP Chapter 797 revision. Board discussion held; Board consensus to monitor future USP developments.

#A15. St. Louis College of Pharmacy Report- Foreign Intern Training Sites/Special Sites

DISCUSSION: St. Louis College of Pharmacy provided information regarding their selection, evaluation and monitoring of foreign intern training sites. Gloria Grice, STLCoP, indicated all foreign training complies with ACPE guidelines for international sites. Additionally, preceptors are English speaking and students have to provide mandatory reports of internship activities. Board discussion held. A student presentation was provided by Adrian Brown regarding her foreign intern training in South Africa; Mrs. Brown indicated the internship was eye-opening and provided valuable patient care experience.

#A16. STLCoP and UMKC College of Pharmacy
- STLCoP Site Listing
- STLCoP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing

DISCUSSION: Tom Glenski recommended approval of both lists. Douglas Lang asked if disciplinary action has been verified for all sites; Tom Glenski reported discipline has been verified by office staff. A motion was made by Christina Lindsay, seconded by Anita Parran, to approve the site/preceptor lists as presented. Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes       Christian Tadrus – yes

#A17. Special Sites/Non-Pharmacist Preceptors

DISCUSSION: Tom Glenski recommended approval of all sites and preceptors listed. A motion was made by Pamela Marshall, seconded by Christina Lindsay, to approve the
special sites/non-pharmacist preceptors listed for 500 hours. Motion passed 4:0:0:1 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

#A19. Kamlesh Trivedi, Disciplinary Hearing, # 040885, #2016-000986

Wednesday, October 25, 2017
3:00 P.M. – 2nd case

DISCUSSION: The Board convened a disciplinary hearing at 3:04 p.m. Alicia Embley-Turner was present as counsel for the Board. Kamlesh Trivedi was present and represented by counsel David Barrett. Both Mr. Barrett and Mrs. Turner provided opening statements and presented exhibits. Closing statements were provided. The hearing adjourned at approximately 4:20 p.m. A transcript of the hearing is available in the Board’s records.

#A11. Inspection/Investigation Report

DISCUSSION: Tom Glenski provided the following updates:

- Inspection/Investigation numbers remained consistent. Board members were provided a report of all continuing education/training programs completed by Board inspectors.
- Katie DeBold and Daniel Vandersand will be attending NABP’s Compliance Officer’s Forum. Andi Miller will be attending the DEA state conference meeting in Dallas.
- Board members inquired about the Board’s participation in NABP’s sterile compounding blueprint program. Kimberly Grinston reported she met with NABP legal counsel Scotti Russell who cross-walked Missouri’s form to the blueprint form. NABP has identified four (4) outstanding Missouri issues: (1) Missouri’s BUD requirements do not comply with USP Chapter 797, (2) Missouri doesn’t require or inspect for the use of sterile gloves, (3) Inspections are not always conducted when compounding is being performed, and (4) Missouri does not require temperature monitoring in all drug storage areas. Mrs. Grinston indicated Missouri’s sterile compounding inspections may not be accepted by other states if Missouri is not part of the blueprint program. Mrs. Grinston reported the temperature issue has been addressed in the revised sterile compounding rule. However, a rule change may be needed to address the other issues identified by NABP. Board discussion held; Board members expressed options may be limited for those issues needing rule changes. Additionally, Board members expressed concerns with noting items on an inspection report that are not required by Missouri law. Board consensus to take no further action at this time but to consider NABP’s identified concerns in future rule discussions.
#A11. Hospital Advisory Committee Update

**DISCUSSION:** Committee Member Bert McClary provided the following updates:

- The Committee will be working with DHSS to review rules as required by SB 501 which preempted designated DHSS rules that duplicate or conflict with CMS Conditions of Participation.
- The next Committee meeting will take place in November. Kimberly Grinston advised the meeting may need to be rescheduled due to a possible conflict.

#A10. General Administration Report (Cont’d)

**DISCUSSION:** Additional Board discussion held on future meeting dates. Board members discussed support for exploring options to more efficiently handle Board agendas and decrease the number of Board meetings, including, delegating additional authority to staff. Board consensus to continue to host conference calls on Wednesdays. Further consensus to check location availability for the following 2018 meeting dates:

- January 10-11, 2018 (Columbia)
- February 7, 2018 (Kansas City)
- April 10-12, 2018 (Columbia)
- August 15, 2018 (Springfield)
- October 24 (Columbia)

THE FOLLOWING ITEMS WERE PROVIDED TO THE BOARD FOR INFORMATIONAL PURPOSES; NO DISCUSSION WAS HELD.

#A21. Board Disciplinary Report

#A23. Board Licensing Statistics

**MOTION TO CLOSE 5:35 P.M.**
At 5:35 p.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), (6), (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
Anita Parran – yes
Douglas Lang- yes
Pamela Marshall – yes
Christina Lindsay – yes

PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 5:35 P.M.
host school’s request, no formal meeting/session was held. Board members individually greeted students during the Board’s scheduled breakfast.

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on October 26, 2017, at approximately 11:46 A.M. All Board members/staff in attendance on October 25, 2017, were also in attendance on October 25, 2017.

MOTION TO ADJOURN 11:46 AM
At approximately 11:46 a.m., a motion was made by Douglas Lang, seconded by Anita Parran, to adjourn the October 2017 meeting. Motion passed 3:0:0:2 with roll call vote as follows:

<table>
<thead>
<tr>
<th>Name</th>
<th>Vote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbara Bilek</td>
<td>absent</td>
</tr>
<tr>
<td>Anita Parran</td>
<td>yes</td>
</tr>
<tr>
<td>Douglas Lang</td>
<td>yes</td>
</tr>
<tr>
<td>Pamela Marshall</td>
<td>yes</td>
</tr>
<tr>
<td>Christina Lindsay</td>
<td>absent</td>
</tr>
</tbody>
</table>

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
#A5. Draft Rule Amendments
(Draft revisions of the following rules are currently under review)

- 20 CSR 2220-2.010 Pharmacy Standards of Operation
- 20 CSR 2220-2.012 Pharmacy Supervision
- 20 CSR 2220-2.090 Pharmacist-In-Charge
- 20 CSR 2220-2.130 Drug Repackaging
- 20 CSR 2220-2.190 Patient Counseling
20 CSR 2220-2.010 Pharmacy Standards of Operation

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

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

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

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

   (C) 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) Required Equipment. Pharmacies must be equipped with properly functioning pharmaceutical equipment for the pharmacy services performed as recognized by the latest edition of the United States Pharmacopeia (USP) or Remington’s Pharmaceutical Sciences. Additionally, pharmacies must have a manual system/device or other equipment for numbering or uniquely identifying prescriptions/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 resource(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. Board-licensed pharmacies shall comply with all applicable state and federal law governing pharmacy practice and medication handling, disposal and distribution. Except as otherwise provided by law or Board rule, pharmacies must ensure:

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

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

(C) All 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 available to the public if requested;

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

(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:

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

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

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

(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 for a time period designated by the Board if such exemption is not contrary to law and the exemption will provide equal or greater protection of the public safety, health or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length and proposed procedures or safeguards for protecting the public safety, health or welfare if the exemption is approved.

20 CSR 2220-2.012 Pharmacy Supervision

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

(1) Definitions. The following definitions apply for purposes of this rule:

(A) “Pharmacy Permit Area”- The portion of the pharmacy premises where prescriptions are processed, compounded, evaluated or dispensed or where legend medication is stored.

(B) “Pharmacy Premises”- The portion of any building or structure leased, used or controlled by the licensee in the conduct of the business regulated by the Missouri Board of Pharmacy at the address for which the permit was issued.

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

(2) Except as otherwise provided in section (4) 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 [physically] present within the pharmacy permit area and able to render immediate assistance and correct errors. Should “physically” present be added? The “except as otherwise provided” language would allow the Board to add remote supervision at a later time.

(A) Pharmacies must maintain current and accurate policies and procedures governing allowed activities and standards for supervision of pharmacy technicians and intern pharmacists. 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.
Except as otherwise provided by law or this rule, pharmacy technicians and intern pharmacist shall be under the direct supervision and responsibility of a pharmacist at all times when assisting in the practice of pharmacy. Except as otherwise authorized by law or rule of the Board, pharmacy technicians may not perform any task or function that requires the professional judgment of a pharmacist including, but not limited to:

(A) Providing patient counseling, including, counseling regarding drug interactions, medication efficacy or appropriateness;

(B) Performing the final medication inspection or verification required by 20 CSR 2220-2.010 or 20 CSR 2220-2.400;

(C) Interpreting prescription or medication orders for therapeutic acceptability or appropriateness;

(D) Receiving prescriptions/medication orders for therapeutic radiopharmaceuticals and blood products;

(E) Independently assigning or determining a beyond use date or expiration date required by Chapter 338, RSMo, or the rules of the Board;

(F) Independently establishing or approving compounding preparation formulations or calculations;

(G) Providing prescriptions to a patient or consumer without a pharmacist’s inspection and verification;

(H) Independently performing or overriding a drug utilization review; Board members asked to amend this to just “drug utilization review.” Did the Board intend to prohibit DUR completely or just independent DURs without a pharmacist’s review?

(I) Professionally advising or consulting with any prescriber, nurse, patient or other person regarding medication efficacy, selection or drug interactions;

(J) Independently interpreting patient laboratory data, diagnostic or medical testing or therapeutic values;

(K) Administering vaccines or other medication;

(L) Modifying drug therapy;

(M) Accepting/Receiving a verbal controlled substance prescription or medication order;

(N) Transferring a controlled substance prescription to another pharmacy; or

(O) Any other task or function that requires the professional judgment of a pharmacist.
(4) 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 from the permit area:

(A) Pharmacist On Premises. Intern pharmacists 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 temporary absence does not exceed thirty (30) minutes and a pharmacist is still present on the pharmacy premises who is able to provide assistance in the event of an emergency.

(B) Pharmacist Not On Premises. If authorized by a pharmacist-in-charge 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:

    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 [physically] 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 does not exempt a permit holder from responsibility for compliance with applicable state or federal law.


20 CSR 2220-2.130 Drug Repackaging

PURPOSE: This rule establishes requirements for drug repackaging.

PUBLISHER’S NOTE: The secretary of state has determined that the publication of the
entire text of the material which is incorporated by reference as a portion of this rule
would be unduly cumbersome or expensive. Therefore, the material which is so
incorporated is on file with the agency who filed this rule, and with the Office of the
Secretary of State. Any interested person may view this material at either agency’s
headquarters or the same will be made available at the Office of the Secretary of State
at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is
printed here. This note refers only to the incorporated by reference material.

(1) A pharmacist or pharmacy may prepackage drugs for other than immediate
dispensing purposes provided that the following conditions are met:
(A) Only products which will be directly provided to the patient may be prepackaged;
(B) Containers utilized for prepackaging shall, at a minimum meet, as a minimum
requirement, that of Class B container standards as referenced by the United States
Pharmacopoeia (USP), which has been incorporated herein by reference. Where
applicable, light sensitive containers must be used;
(C) The maximum expiration date allowed for prepackaged drugs shall be
the manufacturer’s expiration date or twelve (12) months, whichever is less; and
(Should the Board change this standard giving the FDA’s final repackaging guidance
included in the agenda?)
(D) Any prepacked repackaged drug must have a label affixed to it which contains, at
a minimum, the name and strength of the drug, the name of the manufacturer or
distributor, an expiration date as defined in subsection (1)(C) and the manufacturer's
original lot number. The National Drug Code (NDC) may be used in place of the
manufacturer’s or distributor’s name on the label. Pharmacies that store drugs within
an automated counting device may maintain the required lot number and expiration date
in the pharmacy’s records, in place of the required label, maintain records for lot
numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.
(E) Repackaging must be performed using sanitary procedures and under sanitary
conditions. Staff required to touch individual dosage units (e.g., tablets, capsules, etc.)
must wear disposable gloves during the repackaging process. Repackaging of sterile
products or preparations must comply with 20 CSR 2220-2.200

(2) The term prepacked repackaged as used in this rule is defined as any drug which has
been removed from the original manufacturer’s container and is placed in a dispensing
different container for other than immediate dispensing to a patient. This rule does not
apply to return-to-stock prescriptions/medication orders as referenced in 20 CSR 2220-
3.040(3).


20 CSR 2220-2.190 Patient Counseling

PURPOSE: This rule establishes minimum standards for patient counseling to comply with the federal Omnibus Budget Reconciliation Act of 1990 and prospective drug utilization review.

(1) Prospective Drug Utilization Review.
   (A) Prior to dispensing any new prescription or medication order and, if deemed appropriate by the pharmacist, any refill prescription/medication order, the patient’s profile must be reviewed by a pharmacist or an intern pharmacist under the pharmacist’s supervision for:
      (A) Therapeutic duplication;
      (B) Drug-disease contraindication, if applicable;
      (C) Drug-drug interaction;
      (D) Incorrect dosage/duration;
      (E) Drug allergy interactions; and
      (F) Clinical abuse/misuse.
   (B) The pharmacist shall take any action deemed necessary or appropriate in the professional judgment of the pharmacist to address or resolve identified drug utilization concerns or issues. Such action may include, but is not limited to, consulting the prescriber. Nothing in this subsection shall be construed to interfere with or restrict a pharmacist’s exercise of professional judgment or to prohibit dispensing.

(2) Offer to Counsel.
   (A) Except as otherwise provided in section (2)(C), A pharmacist or an intern pharmacist under the pharmacist’s supervision shall personally counsel a patient or caregiver before dispensing any prescription medication, device or equipment to a patient for the first time. This subsection (2)(A) does not apply to a change in dose, strength, route of administration or directions for use or a transferred prescription/medication order that was previously dispensed to the patient for the same medication, device or equipment by another pharmacy.
   (B) Current Therapy. A pharmacist or his/her designee shall personally offer to counsel each patient or caregiver prior to dispensing a prescription/medication order not identified in subsection (2)(A). The offer must be verbally made to the patient or caregiver either in person or electronically (e.g., voice recording/voice announcement).
   (C) If the prescription/medication order is mailed or if the patient or caregiver is not available at the time of dispensing, a written offer to counsel with a toll-free telephone number for the dispensing pharmacy must be supplied for contacting a pharmacist for counseling at no charge to the patient/caregiver.
(D) In addition to the requirements of this rule, pharmacies shall post a manual or electronic sign in a manner clearly visible to the patient indicating that Missouri law requires the pharmacist to discuss with the patient any prescription medication, device or medical equipment being dispensed to the patient for the first time. The required sign must be posted in every prescription/medication pickup area, including any drive-through areas. Pharmacies that provide no direct patient or public access to the pharmacy/ [are not open to the public] are not required to post the required counseling notice (e.g., a “closed-door pharmacy”). [Bd. members asked to use Iowa’s language. Iowa’s Bd. of Pharmacy provides the sign for free. Would the Board do the same?]

(3) Patient counseling shall be conducted by a pharmacist or a pharmacy intern under the pharmacist’s immediate supervision.

(A) Counseling shall include any matter which the pharmacist deems necessary or appropriate in his/her professional judgment to allow the patient to safely and appropriately utilize the prescribed medication, device or medical equipment so that maximum therapeutic outcomes can be obtained. At the pharmacist’s discretion, counseling may include, but is not limited to, the following:

1. The medication name and description;
2. The dosage, dosage form, route of administration and duration of therapy;
3. Any special directions or instructions for patient preparation, administration and use;
4. Significant side effects, adverse effects or interactions, and therapeutic contraindications;
5. Techniques for self-monitoring;
6. Proper storage;
7. Refill information; and
8. Suggested action in the case of a missed dose or equipment/device malfunction.

(B) Counseling must be provided in-person or via an electronic mechanism that allows the pharmacist and patient/caregiver to communicate in real-time either verbally or face-to-face.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples may include, but shall not be limited to, written information leaflets, pictogram labels, video programs, and the like. Licensees shall ensure compliance with all applicable state and federal laws, including, state and federal laws governing patient privacy/confidentiality, medication guides and federal risk evaluation and mitigation strategy (REMS) requirements.

(4) Patient counseling, as described in this rule is not required for inpatients of a hospital, institution or other setting where prescription medication, a device or medical equipment is provided or administered to the patient by other licensed or certified health care professionals.

(5) A pharmacist is not required to counsel a patient or caregiver if the patient or caregiver refuses consultation.
AUTHORITY: sections 338.140 and 338.280, RSMo 2000.* This rule originally filed as 4
CSR 220-2.190. Original rule filed May 1, 1992, effective Feb. 26, 1993. Amended:

#A7. Red Tape Reduction Report/Rule Amendments
#A8. **Staff/Board Member Meetings Report**
- Nuclear Sub-Committee/Updates on revised 20 CSR 2220-2.500
- DMH/NPA Naloxone Training
- Dept. of Health Immunization Training
#A9. **General Administration Report**

- Staff/Office Update
- Financial Report/Technician Renewal Fee
- 2018 Legislation and Budget Requests
- Rule Update (Pending and Red Tape Rule Review)
- Bd. of Healing Arts Review of 20 CSR 2220-6.050
- NABP Annual Meeting (May 5-8 2018 – Denver, Colorado)
#A10. Implementation of SB 501/Rx Cares for Missouri Program
AN ACT
To repeal sections 208.227, 208.790, 208.798, and 334.506, RSMo, and to enact in lieu thereof eight new sections relating to health care.

Section A. Sections 208.227, 208.790, 208.798, and 334.506, RSMo, are repealed and eight new sections enacted in lieu thereof, to be known as sections 196.990, 208.227, 208.229, 208.790, 208.798, 334.506, 338.700, and 338.710, to read as follows:

196.990. 1. As used in this section, the following terms shall mean:
   (1) "Administer", the direct application of an epinephrine auto-injector to the body of an individual;
   (2) "Authorized entity", any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas. "Authorized entity" shall not include any public school or public charter school;
   (3) "Epinephrine auto-injector", a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;
   (4) "Physician", a physician licensed in this state under chapter 334;

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.
(5) Notify the patient's current approved health care provider prior to the continuation of treatment if treatment rendered under this subsection is to continue beyond thirty days. The physical therapist shall provide such notification for each successive period of thirty days.

5. The provision of physical therapy services of evaluation and screening pursuant to this section shall be limited to a physical therapist, and any authority for evaluation and screening granted within this section may not be delegated. Upon each reinitiation of physical therapy services, a physical therapist shall provide a full physical therapy evaluation prior to the reinitiation of physical therapy treatment. Physical therapy treatment provided pursuant to the provisions of subsection 4 of this section may be delegated by physical therapists to physical therapist assistants only if the patient's current approved health care provider has been so informed as part of the physical therapist's seven-day notification upon reinitiation of physical therapy services as required in subsection 4 of this section. Nothing in this subsection shall be construed as to limit the ability of physical therapists or physical therapist assistants to provide physical therapy services in accordance with the provisions of this chapter, and upon the referral of an approved health care provider. Nothing in this subsection shall prohibit an approved health care provider from acting within the scope of their practice as defined by the applicable chapters of RSMo.

6. No person licensed to practice, or applicant for licensure, as a physical therapist or physical therapist assistant shall make a medical diagnosis.

7. A physical therapist shall only delegate physical therapy treatment to a physical therapist assistant or to a person in an entry level of a professional education program approved by the Commission [for] on Accreditation [of] in Physical Therapists and Physical Therapist Assistant Therapy Education (CAPTE) who satisfies supervised clinical education requirements related to the person's physical therapist or physical therapist assistant education. The entry-level person shall be under [on-site] the supervision of a physical therapist.

338.700. As used in sections 338.700 to 338.710, the following terms shall mean:

(1) "Board", the Missouri board of pharmacy;
(2) "Department", the Missouri department of health and senior services;
(3) "Program", the RX cares for Missouri program.

338.710. 1. There is hereby created in the Missouri board of
pharmacy the "RX Cares for Missouri Program". The goal of the
program shall be to promote medication safety and to prevent
prescription drug abuse, misuse, and diversion in Missouri.

2. The board, in consultation with the department, shall be
authorized to expend, allocate, or award funds appropriated to the
board to private or public entities to develop or provide programs or
education to promote medication safety or to suppress or prevent
prescription drug abuse, misuse, and diversion in the state of Missouri.
In no case shall the authorization include, nor the funds be expended
for, any state prescription drug monitoring program including, but not
limited to, such as are defined in 38 CFR 1.515. Funds disbursed to a
state agency under this section may enhance, but shall not supplant,
funds otherwise appropriated to such state agency.

3. The board shall be the administrative agency responsible for
implementing the program in consultation with the department. The
board and the department may enter into interagency agreements
between themselves to allow the department to assist in the
management or operation of the program. The board may award funds
directly to the department to implement, manage, develop, or provide
programs or education pursuant to the program.

4. After a full year of program operation, the board shall prepare
and submit an evaluation report to the governor and the general
assembly describing the operation of the program and the funds
allocated. Unless otherwise authorized by the general assembly, the
program shall expire on August 28, 2019.
Validation of a Screening Risk Index for Overdose or Serious Prescription-Opioid-Induced Respiratory Depression

Barbara Zeidler, MD; William Saunders, PhD, MPH; Andrew Joyce, PhD; Catherine Vick, MS; Lenn Murrelle, MSPh, PhD
Venebio Group, LLC, Richmond, VA; University of North Carolina at Charlotte

BACKGROUND
Prescription opioid use and deaths from overdose or opioid-induced respiratory depression have increased dramatically in the United States since 1999. There were more than 4 times as many opioid-related fatalities in 2010 as there were in 1999 and opioid-related deaths remain at these levels through 2013. Several instruments have been developed to assess the risk of opioid abuse; however, no instruments currently exist that provide useful, real-time, evidence-based information for the healthcare professional regarding the risk of overdose or serious opioid-induced respiratory depression (OSORD) in medical users of prescription opioids. This research builds upon previous work involving the development of a risk index using US Veterans Health Administration (VHA) administrative data to predict a patient’s likelihood of experiencing an OSORD event.

OBJECTIVE
To validate and extend the Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOUSORD) in a larger population more representative of US medical users of prescription opioids.

METHODS

Study Design
Retrospective, nested, case-control study of 18,365,497 US patients with a pharmacy claim for an opioid between January 1, 2009, and December 31, 2013. The study was exempted from IRB review.

Data Source
IMS PharMetrics Plus® is the largest US database of integrated commercial health plan information. It comprises medical and pharmacy claims of 100 companies, as well as 90% of US hospitals and 80% of US physicians.

Study Sample
Study cases were patients who experienced an opioid overdose or life-threatening respiratory or CNS depression event as defined by an algorithm comprising International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) and Current Procedure Terminology (CPT-4) codes. For each case, 4 control patients were randomly selected and assigned from those who did not experience OSORD. The case index date was assigned to each of the 4 control patients.

All eligible cases and controls had non-missing age and sex values, continuous medical/pharmacy benefits during the 6-month baseline period before the index date, and were dispensed at least 1 opioid prescription (excluding cough and cold opioids) during the 6-month baseline period.

Case Definition (Outcome Variable)
An OSORD event was defined as (a) a listed, serious respiratory or CNS adverse effect ICD code (780.0, 780.01-780.03, 780.05, 781.51, 786.82, 786.9, 779.5, 779.01, 779.21) and (b) a listed and opium poison (965.0, 965.05, 965.09, 965.9), or (c) a listing in cardiovascular code (EMS 08260-653, 63950) occurring within 5 days of the adverse event, or (d) use of mechanical ventilation or critical care in addition to a listed opioid poisoning or external cause code occurring within 1 day of the critical respiratory support ICD or CPT code. The first identified event during the study period (index event) served as the index date for cases. Cases that involved heroin alone (965.01 or 965.05) were excluded.

RESULTS

Sample Characteristics
Among the 18 million US patients with an opioid claim during the baseline period, we identified 7,334 case patients who experienced OSORD and 28,932 controls who did not (total N=36,464). Controls and cases, when studied as a group, were not significantly different. The covariates most strongly associated with OSORD included: current smoking, a history of at least 1 opioid prescription in the past 6 months and the highest LOS in the 6-month baseline period before the index date.

Statistical Analysis
• Used multivariable logistic regression to identify the RIOUSORD covariates that were statistically significantly associated with overdose or serious opioid poisoning
• Calculated RIOUSORD scores for cases and controls
• Used multivariable logistic regression to model the risk index scores and OSORD outcome
• Compared the predicted probability of OSORD, by risk class, with the observed incidence in the IMS data set

Table 1. Multivariable Logistic Regression Model: RIOUSORD Covariates

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
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<tbody>
<tr>
<td>Current smoking</td>
<td>1.12</td>
<td>1.06-1.19</td>
<td>0.0001</td>
</tr>
<tr>
<td>History of opioid prescription</td>
<td>1.16</td>
<td>1.11-1.21</td>
<td>0.0001</td>
</tr>
<tr>
<td>Highest LOS in the 6-month baseline period before the index date</td>
<td>1.15</td>
<td>1.10-1.20</td>
<td>0.0001</td>
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Table 2: OSORD Case Patients

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<th>OSORD Category</th>
<th>Number of Cases</th>
<th>Percentage of All OSORD Cases</th>
</tr>
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<tbody>
<tr>
<td>Hypoxemia</td>
<td>3,123</td>
<td>42%</td>
</tr>
<tr>
<td>Opioid toxicity</td>
<td>2,212</td>
<td>30%</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>450</td>
<td>6%</td>
</tr>
<tr>
<td>Resuscitation</td>
<td>53</td>
<td>1%</td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
<td>0%</td>
</tr>
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</table>

CONCLUSIONS

The Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOUSORD) is the first known screening instrument developed to provide real-time, evidence-based information to healthcare professionals regarding the risk of overdose or serious respiratory depression in medical users of prescription opioids. The predictive performance of the RIOUSORD in a large commercial health plan database was excellent and similar to its performance in the VHA database in which it was initially developed. By identifying in this independent database the medical users of prescription opioids who were at increased risk of an event, the strongest predictors were consistent between the VHA and commercial database and included both chronic clinical conditions and characteristics of prescribed medications. Further prospective evaluation and refinement of RIOUSORD in real-world clinical settings, and in clinically defined patient subgroups, should be undertaken.

Patients identified as having elevated risk are most likely to benefit from interventions to mitigate that risk. Such precautions include education of the patient and caregivers, increased caution in opioid selection and dose escalation, consultation with an management specialists, close monitoring for the emergence of OIS or known risk factors for it, as well as prescription of naloxone for administration by family members or caregivers as a rescue medication in the event of a suspected opioid emergency such as overdose.

REFERENCES
4. World Health Organization. Safety and effectiveness of medicinal products during the pregnancy. 1492
5. Drug Safety Update. 1492
7. Poison Data System. 1492

ACKNOWLEDGMENTS AND FUNDING
This research was funded by Venebio, Inc. The study design, analyses, interpretation, and reporting by the study investigators were independently developed by and all analyses were performed by the authors and not by Venebio, Inc. for proprietary information.

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Figure 1. Description of the Risk Index for Serious Prescription-Opioid-Induced Respiratory Depression

Figure 2. Validation of a Screening Risk Index for Overdose or Serious Opioid-induced Respiratory Depression

Figure 3. Predicted probabilities of experiencing overdose or serious respiratory depression were produced from the RIOUSORD scores in the IMS study sample using logistic regression (C-statistics 0.95). The predictive performance of RIOUSORD was assessed by comparing the distribution of predicted probabilities, by percentiles, with the observed incidence of the outcome in the study sample. Among 7 risk classes, the average predicted probability of an event ranged from 2% in the lowest risk class to 83% in the highest, and the observed occurrence of an event increased commensurately (Figure 2).
**Figure 1: Risk Assessment for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD)**

### Step 1: Determine Score for Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD)

<table>
<thead>
<tr>
<th>Question</th>
<th>Points for “Yes” Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the past 6 months, has the patient had a healthcare visit (outpatient, inpatient or ED) involving any of the following health conditions? 2</td>
<td>25</td>
</tr>
<tr>
<td>Substance use disorder (abuse or dependence)?</td>
<td></td>
</tr>
<tr>
<td><em>includes opioids, antidepressants, sedatives/anxiolytics, alcohol, amphetamines, cannabis, cocaine, hallucinogens</em></td>
<td></td>
</tr>
<tr>
<td>Bipolar disorder or schizophrenia?</td>
<td>10</td>
</tr>
<tr>
<td>Stroke (cerebrovascular accident, CVA) or other cerebrovascular disease?</td>
<td>9</td>
</tr>
<tr>
<td>Chronic kidney disease with clinically significant renal impairment?</td>
<td>8</td>
</tr>
<tr>
<td>Heart failure?</td>
<td>7</td>
</tr>
<tr>
<td>Non-malignant pancreatic disease (e.g., acute or chronic pancreatitis)?</td>
<td>7</td>
</tr>
<tr>
<td>Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma, pneumoniaconiosis, asbestosis)?</td>
<td>5</td>
</tr>
<tr>
<td>Chronic headache (e.g., migraine)?</td>
<td>5</td>
</tr>
<tr>
<td>Does the patient consume:</td>
<td></td>
</tr>
<tr>
<td>Fentanyl? (e.g., transdermal or transmucosal immediate-release products)</td>
<td>13</td>
</tr>
<tr>
<td>Morphine?</td>
<td>11</td>
</tr>
<tr>
<td>Methadone?</td>
<td>10</td>
</tr>
<tr>
<td>Hydromorphone?</td>
<td>7</td>
</tr>
<tr>
<td>An extended-release or long-acting (ER/LA) formulation of any prescription opioid, including the above? 3</td>
<td>5</td>
</tr>
<tr>
<td>A prescription benzodiazepine? (e.g., diazepam, alprazolam)</td>
<td>9</td>
</tr>
<tr>
<td>A prescription antidepressant? (e.g., fluoxetine, citalopram, venlafaxine, amitriptyline)</td>
<td>8</td>
</tr>
<tr>
<td>Is the patient’s current maximum prescribed opioid dose ≥ 100 mg morphine equivalents per day? (Include all prescription opioids consumed on a daily basis)</td>
<td>7</td>
</tr>
</tbody>
</table>

**Total point score (maximum 146)**

### Step 2: Identify Risk Class for OSORD

<table>
<thead>
<tr>
<th>Risk Class</th>
<th>RIOSORD Score (Points)</th>
<th>Average Probability of OSORD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0-4</td>
<td>2%</td>
</tr>
<tr>
<td>2</td>
<td>5-7</td>
<td>5%</td>
</tr>
<tr>
<td>3</td>
<td>8-9</td>
<td>7%</td>
</tr>
<tr>
<td>4</td>
<td>10-17</td>
<td>15%</td>
</tr>
<tr>
<td>5</td>
<td>18-25</td>
<td>30%</td>
</tr>
<tr>
<td>6</td>
<td>26-41</td>
<td>55%</td>
</tr>
<tr>
<td>7</td>
<td>≥42</td>
<td>83%</td>
</tr>
</tbody>
</table>

OSORD, overdose or serious opioid-induced respiratory depression

2This questionnaire is intended for completion and interpretation by a healthcare professional. It is not a replacement for clinical judgment and is intended to guide and inform clinical decision-making for patients who are prescribed opioids.

3A patient consuming 1 or more opioids with an ER/LA formulation receives 5 additional points for 'ER/LA formulation of any prescription opioid' regardless of the number of different ER/LA products consumed.

"This condition does not have to be the primary reason for the visit but should be entered in the chart or EHR as one of the reasons or diagnoses for the visit.

1This question is intended to be completed and interpreted by a healthcare professional. It is not a replacement for clinical judgment and is intended to guide and inform clinical decision-making for patients who are prescribed opioids.
#A12. Fiscal Year 2018-2019 Strategic Plan

- 2017 Strategic Plan Draft
- California Board of Pharmacy Strategic Plan
The Board has been asked to reconsider 20 CSR 2220-2.200(20)'s requirement that pharmacies terminate compounding if a positive test identified in subsection (20) is discovered if a highly pathogenic microorganism is detected.
RSMo will be open to any member of the public.

(2) The Board of Pharmacy establishes the executive director of the board as the custodian of its records as required by section 610.023, RSMo. The executive director is responsible for the maintenance of the board's records and is responsible for responding to requests for access to public records.

(3) When a request for inspection of public records is made and the individual inspecting the records requests copies of the records, the board will collect the appropriate fee for costs for inspecting and copying of the records, as outlined in the board's fee rule, 4 CSR 220-4.020. The board may require payment of the fees prior to making available any public records.

(4) When a request for access to public records is made and the custodian believes that access is not required under the provisions of Chapter 610, RSMo, the custodian shall inform the individual or entity making the request that compliance with the request cannot be made, specifying in particular what sections of Chapter 610, RSMo require that the record remain closed. Any such correspondence or documentation of the denial made for access to records shall be copied to the Board of Pharmacy general counsel. Whenever the custodian denies access to the records, the custodian also shall inform the individual requesting the records that s/he may appeal directly to the Board of Pharmacy for access to the records requested. The appeal and all information pertaining to the appeal shall be placed on the meeting agenda of the Board of Pharmacy for its next regularly scheduled meeting. In the event that the board decides to reverse the decision of the custodian, the board shall direct the custodian to so advise the person requesting access to the information and supply the access to the information during regular business hours at the convenience of the requesting party.

(5) The custodian shall maintain a file which will contain copies of all written requests for access to records and responses to the requests. These requests shall be maintained on file with the board for a period of one (1) year and will be maintained as a public record of the board open for inspection by any member of the general public during regular business hours.

(6) Pursuant to section 620.111, RSMo any complaints, investigation reports and accompanying documents or exhibits that are considered closed documents under Chapter 610 or 620, RSMo, and are possessed by the board or any of its agents shall not be disclosed to any member of the public or to a licensee until the investigation is completed.

(A) Federal or state agency documents shall not be released without the written consent of the federal or state agency involved.


20 CSR 2220-2.190 Patient Counseling

PURPOSE: This rule establishes minimum standards for patient counseling to comply with the federal Omnibus Budget Reconciliation Act of 1990 which requires that all states establish standards by January 1, 1993.

(1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist’s immediate supervision to allow the pharmacist for counseling when necessary. In situations where automated pick-up systems are used for providing refill prescriptions to patients, the offer to counsel may be provided within the information provided by the kiosk to the patient during the processing phase prior to release of the medication to the patient. The elements of counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

(2) Pharmacies shall maintain appropriate patient information to facilitate counseling. This may include, but shall not be limited to, the patient’s name, address, telephone number, age, gender, clinical information, disease states, allergies and a listing of other drugs prescribed.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples may include, but shall not be limited to, written information leaflets, pictogram labels, video programs, and the like.

(4) Patient counseling, as described in this rule, shall not be required for inpatients of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications.

(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation.


20 CSR 2220-2.200 Sterile Compounding

PURPOSE: This rule establishes standards for the handling, labeling, distribution, and dispensing of compounded sterile preparations by licensed pharmacies, pursuant to a physician’s order or prescription.

PUBLISHER’S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Definitions.

(A) Aseptic processing: The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

(B) Batch: Compounding of multiple sterile preparation units in a single discrete process, by the same individuals, carried out...
during one (1) limited time period.

(C) Beyond-Use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(D) Biological safety cabinet: Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the preparation, personnel, and environment, according to National Sanitation Foundation (NSF) International standards.

(E) Buffer area: An ISO Class 7 or better area where the primary engineering control is physically located that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

(F) Compounding: For the purposes of this regulation, compounding is defined as in 20 CSR 2220-2.400(1). Compounded sterile medications may include, but are not limited to:

1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that must or are required to be sterile when they are administered to patients, including, but not limited to, the following dosage forms: bronchial and inhaled nasal preparations intended for deposition in the lung(s), baths and soaks for live organs and tissues, epidural and intrathecal solutions, bladder/wound solutions, injectable, implantable devices and dosage forms, inhalation solutions, intravenous solutions, irrigation solutions, ophthalmic preparations, parenteral nutrition solutions, and repackaged sterile preparations. Nasal sprays and irrigations intended for deposit in the nasal passages may be prepared as nonsterile compounds;

2. An FDA approved manufactured sterile product that is either prepared according to the manufacturers’ approved labeling/recommendations or prepared differently than published in such labeling; and

3. Assembling point-of-care assembled systems.

(G) Compounding aseptic containment isolator (CACI): A restricted access barrier system (RABS) that is designed for compounding sterile hazardous drugs and designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment for Compounded Sterile Preparation (CSPs).

(H) Compounding aseptic isolator (CAI): A RABS specifically designed for compounding sterile non-hazardous pharmaceutical ingredients or CSPs and designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.

(I) Controlled area: For purposes of these regulations, a controlled area is a separate room designated for preparing sterile preparations or an area designated for preparing sterile preparations that is separated from other activities/operations by a line of demarcation that clearly separates the area from other operations.

(J) Critical area: Any area in the controlled area where preparations or containers are exposed to the environment.

(K) Critical site: Any surface, pathway, or opening (e.g., vial septa, injection ports, beakers, needle hubs) that provides a direct pathway between a compounded sterile preparation or other ingredient used to compound a sterile preparation and the air, environment or moisture, or that poses a risk of touch contamination.

(L) CSP: Compounded sterile preparation.

(M) Cytotoxic drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system, and the alteration of a host’s inflammatory response system.

(N) Emergency dispensing: Is a situation where a Risk Level 3 preparation is necessary for immediate administration of the preparation and no alternative product or preparation is available and the prescriber is informed that the preparation is being dispensed prior to appropriate testing. Documentation of the dispensing of the preparation, the prescriber’s approval for dispensing prior to the receipt of test results and the need for the emergency must appear within the prescription record. A separate authorization from the prescriber is required for each emergency dispensing.

(O) High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal- or vertical-laminar-airflow workbench, an environment can be created consistent with standards for an ISO Class 5 environment.

(P) In-use time/date: The time/date before which a conventionally manufactured product or a CSP must be used after it has been opened or needle-punctured.

(Q) ISO Class 5: An area with less than three thousand five hundred twenty (3,520) particles (0.5 μm and larger in size) per cubic meter.

(R) ISO Class 7: An area with less than three hundred fifty-two thousand (352,000) particles (0.5 μm and larger in size) per cubic meter.

(S) Multiple-dose container: A multiple unit container for articles or compounded sterile preparations that contains more than one (1) dose of medication and usually contains an antimicrobial preservative.

(T) Parenteral: A sterile preparation of drugs for injection through one (1) or more layers of skin.

(U) Point-of-care assembled system: A closed system device that creates a physical barrier between diluents, fluids, or other drug components and is designed to be activated by the end user by allowing the components to mix prior to administration.

(V) Primary engineering control (PEC): A system that provides an ISO 5 environment for the exposure of critical sites when compounding sterile preparations. PECs include, but may not be limited to, horizontal/vertical laminar airflow hoods, biological safety cabinets, and a RABS such as compounding aseptic isolators (CAIs), or compounding aseptic containment isolators (CACIs).

(W) Process validation or simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the preparation and with the same container or closure system.

(X) Quality assurance: For purposes of these regulations, quality assurance is the set of activities used to ensure that the processes used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.

(Y) Quality control: For the purposes of these regulations, quality control is the set of testing activities used to determine that the ingredients, components, and final sterile preparations prepared meet predetermined requirements with respect to identity, purity, nonpyrogenicity, and sterility.

(Z) Restricted access barrier system (RABS): A primary engineering control that is comprised of a closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides...
HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits. Examples of a RABS may include, but is not limited to, a CAI or CACI.

(AA) Repackaging: The subdivision or transfer of a compounded preparation from one (1) container or device to a different container or device.

(BB) Single-dose/single-unit container/vial: A container/vial of medication intended for administration that is meant for use in a single patient for a single case, procedure, or injection.

(CC) Sterilization: A validated process used to render a preparation free of viable organisms.

(DD) Temperatures:
1. Frozen means temperatures between twenty-five degrees below zero and ten degrees below zero Celsius (-25 and -10°C) (thirteen degrees below zero and fourteen degrees Fahrenheit (-13 and 14°F));
2. Refrigerated means temperatures between two and eight degrees Celsius (32 and 8°C) (thirty-six and forty-six degrees Fahrenheit (36 and 46°F)); and
3. Controlled room temperature means a temperature maintained thermostatically that encompasses the usual and customary working environment 20° to 25° Celsius (68° to 78° F). Excursions between 15° and 30° Celsius (59° to 86°F) as commonly experienced in pharmacies and other facilities shall be deemed compliant.

(EE) USP: The United States Pharmacopeia and the National Formulary (USP-NF) as adopted and published by the United States Pharmacopeial Convention, effective May 2013. Copies of the USP-NF are published by, and available from, USP, 12601 Twinbrook Parkway, Rockville, MD 20852-1790 or online at http://www.usp.org/. The USP-NF is incorporated herein by reference. This rule does not include any later amendments or additions to the USP-NF.

(FF) Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a preparation meeting predetermined specifications and quality attributes.

(GG) Definitions of sterile compounded preparations by risk level:
A. Preparations:
   1. Risk Level 1: Applies to compounded sterile preparations that exhibit characteristics A., B., or C., stated below. All Risk Level 1 preparations shall be prepared with sterile equipment and sterile ingredients and solutions in an ISO Class 5 environment. Risk Level 1 includes the following:
   A. Preparations:
      1. Stored at controlled room temperature and assigned a beyond-use date of forty-eight (48) hours or less; or
      2. Stored under refrigeration and assigned a beyond-use date of seven (7) days or less; or
      3. Stored frozen and assigned a beyond-use date of thirty (30) days or less;
   B. Unpreserved sterile preparations prepared for administration to one (1) patient or batch-prepared preparations containing suitable preservatives prepared for administration to more than one (1) patient with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule;
   C. Preparations prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule;
   2. Risk Level 2: Sterile preparations exhibit characteristic A., B., or C., stated below. All Risk Level 2 preparations shall be prepared with sterile equipment and sterile ingredients in an ISO Class 5 environment and with closed-system transfer methods. Risk Level 2 includes the following:
      A. Preparations stored under refrigeration and assigned a beyond-use date greater than seven (7) days, or preparations stored frozen and assigned a beyond-use date greater than thirty (30) days, or preparations stored at controlled room temperature and assigned a beyond-use date greater than forty-eight (48) hours;
      B. Batch-prepared preparations without preservatives that are intended for use by more than one (1) patient;
      C. Preparations compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounding);
   3. Risk Level 3: Sterile preparations exhibit either characteristic A. or B.:
      A. Preparations compounded from nonsterile ingredients or compounded with nonsterile components, containers, or equipment before terminal sterilization;
      B. Preparations prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

(2) Policy and Procedure Manual/Reference Manuals:
A. A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2, and 3 compounding performed, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis. The pharmacy shall have current reference materials related to sterile preparations.

(3) Personnel Education, Training, and Evaluation:
A. Risk Level 1: All pharmacy personnel preparing sterile preparations must receive appropriate didactic and experiential training in aseptic technique and procedures and shall be skilled and trained to accurately and competently perform the duties assigned. Additional training must be provided if the risk level of sterile activity conducted by the individual changes or if there is a change in compounding methods performed. To ensure competency, individuals preparing sterile preparations must successfully pass an Aseptic Technique Skill Assessment that complies with section (10) of this rule. The pharmacy shall establish policies and procedures for staff training and assessment.

B. Risk Level 2: In addition to Risk Level 1 requirements, personnel training must include assessment of competency in all Risk Level 2 procedures via process simulation.
C. Risk Level 3: In addition to Risk Level 1 and 2 requirements, operators have specific education, training, and experience to prepare Risk Level 3 preparations. The pharmacist knows principles of good compounding practice for risk level preparations, including—
   1. Aseptic processing;
   2. Quality assurance of environmental, component, and end-preparation testing;
   3. Sterilization; and
   4. Selection and use of containers, equipment, and closures.

(4) Storage and Handling in the Pharmacy:
A. Risk Level 1 and 2: Solutions, drugs, supplies, and compounding equipment must be stored and maintained in a manner that will maintain the chemical and microbiological stability of CSPs. Refrigeration, freezer and, if applicable, incubator temperatures shall be documented daily. Other storage areas shall be inspected regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be shelved above the floor. Removal of drugs and supplies from boxes shall be done outside the controlled and buffer areas. Removal of used supplies from the controlled area shall be
done at least daily. Preparation recall procedures must comply with section (21) of this rule and must permit retrieving affected preparations from specific involved patients.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, the pharmacy must establish procedures for procurement, identification, storage, handling, testing, and recall of components and finished preparations. Finished Risk Level 3 preparations awaiting test results must be quarantined under minimal risk for contamination in a manner that will maintain chemical and microbiological stability.

(5) Facilities and Equipment. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas. The identity of the pharmacist conducting the required review and the review date shall be documented in the pharmacy’s records.

(A) Risk Level 1: Risk Level 1 preparations must be prepared in a PEC located in a controlled area that meets the requirements of this rule. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected as provided in section (17) of this rule. Activities within the critical area shall be kept to a minimum to maintain the ISO classified environment. Primary engineering controls shall meet the requirements of section (6) of this rule; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer’s specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, Risk Level 2 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. Applicable environmental monitoring of air and surfaces must be conducted. Risk Level 2 preparations shall at a minimum remain a Risk Level 2 for the life of the preparation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, Risk Level 3 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. All non-sterile equipment that is to come in contact with the sterilized final preparation must be sterilized before introduction in the buffer area or into the RABS. Once compounded, Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of the preparation.

(D) Automated compounding devices shall be calibrated according to manufacturer procedures for content, volume, weight, and accuracy prior to initial use and prior to compounding each day the device is in use or more frequently as recommended by manufacturer guidelines. Calibration results shall be reviewed by a pharmacist to ensure compliance. The identity of the reviewing pharmacist and the review date shall be documented in the pharmacy’s records.

(E) All PECs and ISO classified areas shall be certified to ensure compliance with the requirements of this rule prior to beginning sterile compounding activities and every six (6) months thereafter. Certification shall be conducted by competent staff/vendors using recognized and appropriate certification and testing equipment. Certification results shall be reviewed by a pharmacist once received. Deficiencies or failures shall be investigated and corrected prior to further compounding which may include recertification of the PEC/ISO classified area.

1. The PEC and ISO classified areas must be recertified when— 1) any changes or major service occurs that may affect airflow or environmental conditions or 2) the PEC or room is relocated or the physical structure of the ISO classified area has been altered.

2. Corrections may include, but are not limited to, changes in the use of the affected PEC or ISO classified area or initiating a recall.

(F) Pressure differential: If the sterile compounding area is equipped with a device to monitor pressure differential between ISO classified air spaces, pressure differential results must be recorded and documented each day that the pharmacy is open for pharmacy activities. Alternatively, a continuous monitoring system may be used to record pressure differential results if the system maintains ongoing documentation of pressure recordings or maintains pressure alerts that are reviewed daily.

(6) Primary Engineering Controls (PECs).

(A) PECs must be properly used, operated, and maintained and must be located out of traffic patterns and away from conditions that could adversely affect their operation or disrupt intended airflow patterns (e.g., ventilation systems or cross-drafts).

(B) PECs shall maintain ISO Class 5 or better conditions during dynamic operating conditions and while compounding sterile preparations, including, when transferring ingredients into and out of the PEC and during exposure of critical sites.

(C) PECs shall provide unidirectional (laminar flow) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.

(D) The recovery time to achieve ISO Class 5 air quality in any PEC shall be identified in the pharmacy’s policies and procedures. Procedures must be developed to ensure adequate recovery time is allowed before or during compounding operations and after material transfer.

(7) Controlled Areas. The controlled area shall be designed, maintained, and controlled to allow effective cleaning and disinfection and to minimize the risk of contamination and the introduction, generation, and retention of particles inside the PEC.

(A) Controlled areas must be clean and well-lit and shall be free of insects, rodents, and/or other vermin. Trash shall be disposed of in a timely and sanitary manner and at least daily. Tacky mats or similar articles are prohibited in the controlled area or any ISO classified environment.

(B) Traffic flow in or around the controlled area shall be minimized and controlled. Food items, chewing gum, eating, drinking, and smoking are prohibited in the area.

(C) Non-essential objects that shed particles shall not be brought into the controlled area, including, but not limited to, pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads). Furniture, carts, supplies, and equipment shall be removed from shipping cartons/containers and properly cleaned and disinfected with sterile alcohol or an equivalently effective non-residue generating disinfectant before entering any ISO classified area. No shipping or other external cartons may be taken into the controlled area or an ISO classified area.

(D) Only supplies essential for compounding shall be stored in the controlled area. Supplies or other non-essential equipment shall not be stored in or on the PEC.

(8) Garbing and Hand Hygiene. Individuals engaged in, or assisting with, CSPs shall be trained and demonstrate competence in proper personal garbing, gloving, and hand hygiene. Competence must be documented and assessed through direct visual observation as part of the aseptic technique skill assessment required by this rule.

(A) Risk Level 1: Low-particulate and non-shedding gowns, hair covers, gloves, face masks, and, if applicable, beard covers must be worn during compounding and cleaning. All head and facial hair must be covered. During sterile preparation, gloves shall be disinfected before use and frequently thereafter with a suitable agent and changed when integrity is compromised. All personnel in the controlled area must be appropriately
garbed as required by this section.

(B) Risk Level 2 and Risk Level 3: In addition to Risk Level 1 requirements, shoe covers and sterile gloves must be worn while compounding and cleaning, including, over RABS gloves. All personnel in the controlled or buffer area must garb as required by this section.

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

(A) Risk Level 1: Sterile preparations must be prepared in an ISO Class 5 environment. Personnel shall scrub their hands and forearms a minimum of thirty (30) seconds and remove debris from underneath fingernails under warm running water before donning the required gloves. Eating, drinking, and smoking are prohibited in the controlled area.

Talking shall be minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible, and appropriate for the preparation to be prepared, according to manufacturer, USP, or scientific references. Ingredients and containers shall be inspected for defects, expiration, and integrity before use. Only materials essential for aseptic compounding shall be placed in the PEC. Supplies, equipment, and the surfaces of ampules and vials shall be disinfected before entering the PEC by wiping the outer surface with sterile alcohol or an equivalent effective non-residue generating disinfectant. Sterile components shall be arranged in the PEC to allow a clear, uninterrupted path of HEPA-filtered air over critical sites. Automated devices and equipment shall be cleaned, disinfected, and placed in the PEC to enable laminar airflow. Aseptic technique shall be used to avoid touch contamination of critical sites of containers and ingredients. Particles shall be filtered from solutions, if applicable. Needle cores shall be avoided. The pharmacist shall check before, during, and after preparation to verify the identity and amount of ingredients before release.

(B) Risk Level 2: In addition to Risk Level 1 requirements, a file containing the formula, components, procedures, sample label, and final evaluation shall be made for each preparation batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile preparations, a second verification of calculations shall take place. The pharmacist shall verify data entered into any automatic compounder before processing and check the end preparation for accuracy.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet compendial standards or must be verified by a pharmacist and a certificate of analysis. Batch preparation files shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used when feasible. Final containers must be sterile and capable of maintaining preparation integrity throughout the shelf life. Sterilization methods must be based on properties of the preparation, and must be conducted in a method recognized by USP for the preparation and confirmed through sterility testing using a testing method recognized by USP for the preparation.

(D) Single-dose vials/containers and pharmacy bulk vial/containers exposed to ISO Class 5 or cleaner air may be used in compounding until the assigned in-use time which shall not exceed six (6) hours after initial needle puncture, unless otherwise specified by the manufacturer. Opened single-dose ampules shall not be stored for any time period. The in-use time must be placed on the vial/container.

(E) Unless otherwise specified by the manufacturer, multiple-dose vials/containers with an antimicrobial preservative may be used in compounding until the assigned in-use date which shall not exceed twenty-eight (28) days after initially entering or opening the vial/container (e.g., needle-puncture). The in-use date must be placed on the vial/container.

(10) Aseptic Technique Skill Assessment. Individuals engaged in sterile compounding must take and successfully pass an aseptic technique skill assessment to verify aseptic competency. The assessment must include a direct visual observation of the individual's aseptic competency during a process simulation that represents the most challenging or stressful conditions encountered or performed by the person being evaluated. The assessment must include media-fill testing for all risk levels performed. Self-observation is not allowed.

(A) The required visual observation shall assess:

1. Proper aseptic technique, manipulations, and work practices, including, but not limited to, avoiding touch contamination, proper use of first air, and if applicable, sterilizing high risk CSPs;
2. Cleaning and disinfection;
3. Hand hygiene, gloving, and gardening;
4. Identifying, weighing, and measuring of ingredients;
5. Maintaining sterility in ISO Class 5 areas;

(B) Media-Fill Testing. Pharmacies shall establish and follow policies and procedures for media-fill testing. Media-fill testing shall comply with USP Chapter 797’s recommended procedures and methods and must be conducted using the most challenging or stressful conditions/compounding actually encountered or performed by the person being evaluated using the same container or closure. A minimum of three (3) media-fill tests must be completed during initial media-fill testing and one (1) media-fill test completed for ongoing testing.

(C) Frequency: The required Aseptic Technique Skill Assessment must be conducted prior to initial compounding and every twelve (12) months thereafter for Risk Levels 1 and 2 compounding and every (6) months thereafter for Risk Level 3 compounding. Additionally, an Aseptic Technique Skill Assessment must be conducted whenever unacceptable techniques are observed or discovered, if the risk level of sterile activity conducted by the individual changes, or if there is a change in compounding methods performed.

(D) Individuals who fail written tests; visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must undergo immediate requalification through additional training by competent personnel. Individuals who fail visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must pass a reevaluation in the deficient area before they can resume compounding of sterile preparations. Individuals who fail media-fill testing must pass three (3) successive media-fill tests prior to resuming sterile compounding.

(11) Record Keeping.

(A) Risk Level 1 and 2: The following must be documented/maintained:

1. Training and competency evaluation of pharmacy personnel involved in sterile compounding, including, the dates and results of the required aseptic technique training, aseptic technique skill assessment, and media-fill testing;
2. Refrigerator, freezer and, if applicable, incubator temperature logs;
3. Certification dates and results for any PEC or ISO classified area;
4. Manufacturer manuals that are relied upon to maintain compliance with this rule;
5. Other facility quality control logs, as appropriate, including all maintenance, cleaning, and calibration records;
6. If applicable, pressure recordings including documentation of the review of continuous monitoring system results as required by subsection (5)(F);
7. Any end-preparation testing records; and

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk Level 3 preparations must include:
1. Preparation work sheet;
2. Sterilization records;
3. Quarantine records, if applicable;
4. End-preparation evaluation and testing records as required in section (14); and
5. Ingredient validation records as required in section (14).

(C) All records and reports shall be maintained either electronically or physically for two (2) years and shall be readily retrievable and subject to inspection by the board of pharmacy or its agents. At a minimum, records shall be physically or electronically produced immediately or within two (2) hours of a request from the board or the board’s authorized designee.

12. Labeling.

(A) Sterile preparations shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information:
1. Beyond-use date;
2. Storage requirements if stored at other than controlled room temperature;
3. Any device specific instructions;
4. Auxiliary labels, when applicable; and
5. If applicable, a designation indicating the preparation is hazardous.


(A) Risk Level 1 and Risk Level 2: All sterile preparations must bear a beyond-use date. Beyond-use dates must be assigned based on current drug and microbiological stability information and sterility considerations.

(B) Risk Level 3: In addition to all Risk Level 1 requirements, the risk prediction procedure shall be supplemented with a program of post-preparation sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batches shall be established if preparation testing results are unacceptable. A sample from each sterile preparation/batch must be tested for sterility. A sample from each parenteral sterile preparation/batch must also be tested for pyrogenicity. Risk Level 3 preparations must be quarantined and stored to maintain chemical and microbiological stability pending results of end-preparation testing.

1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of preparation. The sterility test, including the sampling scheme, shall be conducted in accordance with a method recognized by the USP Chapter 71.
2. Pyrogen testing: Sterile parenteral preparations prepared from non-sterile bulk active ingredients shall be tested for pyrogen or endotoxin according to a method recognized by USP Chapter 151 for pyrogen testing and recognized by USP Chapter 85 for endotoxin testing.
3. Potency: The pharmacy shall have a procedure for a pre-release check of the potency of the active ingredients in the compounded sterile preparation prepared from non-sterile bulk active ingredients. The procedure shall include at least the following verifications by a pharmacist:
   A. The lot of the active ingredients used for compounding have the necessary labeling, potency, purity, certificate of analysis, and other relevant qualities;
   B. All weighings, volumetric measurements, and additions of ingredients were carried out properly;
   C. The compounding or control records include documentation that the fill volumes of all units available for release were checked and were correct; and

D. The final potency is confirmed by instrumental analysis for sterile preparations that have been assigned a beyond-use date of more than thirty (30) days.

(D) Emergency Dispensing of a Risk Level 3 Sterile Preparation: When a compounded Risk Level 3 preparation must be released prior to the completion of testing, the sterile preparation may be dispensed pending test results. Emergency dispensing shall be defined as, and comply with, subsection (1)(N) of this rule.

15. Storage, Handling, and Transport. Sterile preparations shall be packaged, stored, dispensed, and distributed in a manner that will maintain the preparation's chemical and microbiological stability until the prescribed expiration date or until delivery to the patient or intended recipient. The pharmacist-in-charge shall assure the environmental control of all sterile compounded preparations shipped. Sterile preparations shall be transported so as to be protected from excesses of temperature and light within appropriate packaging or delivery containers that maintain necessary storage conditions to preserve the quality and integrity of sterile preparations. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of preparations with common storage characteristics and for specific preparations where unique storage conditions are required to retain adequate stability and preparation quality.

16. Point-of-Care Assembled Systems. Assembly of point-of-care assembled systems shall be considered Risk Level 1 compounding. Point-of-care assembled systems shall be assigned a beyond-use date which may exceed the beyond-use date authorized for Risk Level 1 preparations provided the date is assigned in accordance with the manufacturer's recommendations or labeling.

(A) When dispensed, an assembled non-activated system shall be labeled with beyond-use dates for both activated and non-activated states. The compounding record must document both dates. The beyond-use date of an assembled non-activated system shall be limited to a maximum of fifteen (15) days unless the pharmacy has documentation from the system's manufacturer that a longer date is acceptable.

(B) Point-of-care assembled systems shall be assembled and stored in accordance with the manufacturer's labeling and recommendations.

17. General Cleaning and Disinfection
(18) Environmental Sampling/Testing. The pharmacy shall establish and follow proper cleaning and disinfection procedures described in the pharmacy’s written policies and procedures. Manufacturers’ directions for minimum contact time shall be followed. 

(D) All cleaning tools (e.g., wipes, sponges, and mop heads) must be low-lint and dedicated for use in the controlled area and ISO classified areas.

(E) Primary engineering controls shall be cleaned with a germicidal agent followed by sterile alcohol. Sterile water for irrigation shall be used to dilute germicidal agents used inside the PEC that require dilution.

(F) At a minimum, the critical area shall be cleaned and disinfected prior to compounding, between batches, and whenever contamination is suspected using sterile alcohol which is allowed to dry immediately prior to compounding.

(19) Cytotoxic Drugs.

(A) The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved: 

1. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet or a CACI. If used for other preparations, the cabinet must be thoroughly cleaned.

2. Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves, and gowns with tight cuffs.

3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations. Chemotherapy preparations should be compounded using a closed system transfer device;

4. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious waste from patients’ homes. Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements;

5. Written procedures for handling major and minor spills and generated waste of cytotoxic agents must be developed and must be included in the policy and procedure manual; and 

6. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

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

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

(21) Recalls. A recall must be initiated when a dispensed CSP is deemed to be misbranded, adulterated, or non-sterile or if end-preparation testing results are out of specification. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified, and any recommended actions to ensure public health and safety. In cases where the CSP has the potential to harm the patient, the same notification shall be provided to all patients that received the recalled CSP(s). Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days. The pharmacy shall document their activities related to the recall.


DISCUSSION: At the Board's request, UMKC School of Pharmacy will be presenting general information on their foreign intern training sites, including, site/preceptor selection and screening procedures. Students have also been asked to present on their foreign intern site experiences.