MEETING NOTICE  
Missouri Board of Pharmacy  
CONFERENCE CALL  

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

February 13, 2019  
3:00 p.m.  

Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 3:00 p.m. on February 13, 2019 via conference call. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 3:00 p.m. on February 13, 2019. They may also call 573-526-5808 (local) or 866-630-9351 (toll-free).  

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes pursuant to Section 610.021(1), (13) and (14) and section 324.001.8, RSMo. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.  

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.
MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

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

February 13, 2019
3:00 p.m.

OPEN SESSION AGENDA

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

2. Roll Call

3. Approval of Minutes

4. Revisions to 20 CSR 2220-2.500 (Nuclear Pharmacy)
   • Draft Rule

5. Revisions to 20 CSR 2220-2.400 (Compounding Standards of Practice)
   • Update on Missouri Veterinary Board Meeting
   • Draft Rule

6. 2019 Legislation
   • HB 487 (Contraceptives)
   • HB 667 (Foreign Distributors)
   • HB 727 (Dispensing on Hospital Discharge)
   • SB 127 (Importation Study)
   • SB 274 (Pharmacy Pilot Projects)
   • SB 275 (Dentist Prescribing)
   • SB 309 (Tobacco Cessation)
   • Draft Pharmacist Scope of Practice
   • Board Legislation

7. Rx Cares for Missouri/Medication Destruction Request for Proposals

8. Chapter 338, RSMo Standards/Scope of Practice Review

9. Special Sites
   • Cox Health Center Steeplechase
   • Eli Lilly
   • Pharm to Farm
   • Providence Family Medicine
• Quentin N. Burdick Memorial Health Center
• Strand Clinical Technologies
• Tria Health
• UMKC School of Pharmacy at MSU
• Winslow Indian Health

10. FY18 Annual Report
   • Draft FY18 Report

11. Final Order of Rulemaking 20 CSR 2220-8.040 (Standards of Operations for Drug Outsourcers)

12. Future Meeting Dates/Times

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

14. Adjournment
#3 Approval of Minutes

- January 25, 2019 (E-Mail Ballot)
Board Members Voting
Douglas R. Lang, R.Ph., Vice-President
James Gray, R.Ph, Member
Pamela Marshall, R.Ph, Member
Anita Parran, Public Member

#C1 Xcenda

ITEMS ENCLOSED:
- Special Site Application

RECOMMENDATION:
Xcenda: Approve for 500 hours

Votes:
Douglas R. Lang—Approved
James Gray—Approved
Pamela Marshall—Approved
Anita Parran—Approved

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Approved:
#4. **Revisions to 20 CSR 2220-2.500 (Nuclear Pharmacy)**  
- Draft Rule
20 CSR 2220-2.500 Nuclear Pharmacy- Minimum Standards for Operation

PURPOSE: This rule defines minimum standards for the operation of nuclear pharmacies and
the preparation, labeling, dispensing, delivering, compounding, and repackaging of
radiopharmaceuticals pursuant to a prescription drug or medication order. This regulation is
intended to supplement other regulations of the Board of Pharmacy, as well as those of
other state and/or federal agencies.

(1) Definitions.

(A) “Authorized address or location” means the building or buildings that are identified
on the license and where byproduct material may be received, prepared, used, or stored as
defined by 10 CFR 35.2 or a temporary job site for providing mobile nuclear medicine services
in accordance with 10 CFR 35.80.

(B) “Agreement state” means any state that has entered into an agreement under
subsection 274b of the Atomic Energy Act of 1954, as amended, in which the United States
Nuclear Regulatory Commission has relinquished to such states the majority of its regulatory
authority over source material, by-product, and special nuclear material in quantities not
sufficient to form a critical mass.

(C) “Authentication of product history” means identifying the purchasing source, the
ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other
drug.

(D) “Authorized nuclear pharmacist” (ANP) means a pharmacist who holds a current
license issued by the board and who is either certified as a nuclear pharmacist by the Board
of Pharmacy Specialties, has attained status as an authorized nuclear pharmacist or an
authorized user of radioactive material, as specified by the Nuclear Regulatory Commission or
Agreement State regulations, including, but not limited to, 10 CFR 35.55, 35.57 and 35.59.

(E) “Contingency prescription drug order” means a radioactive prescription drug order
issued for contingency material for a diagnostic purpose.

(F) “Controlled access area” means an area outside of the restricted area but inside the
pharmacy, access to which will be limited to the public.

(G) “Practice of nuclear pharmacy” means a patient-oriented service that embodies the
scientific knowledge and professional judgment required to improve and promote health through
the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(H) “NRC” means the United States Nuclear Regulatory Commission.

(I) “Nuclear pharmacy” means the location that provides radiopharmaceutical services
and where radiopharmaceuticals and chemicals within the classification of legend drugs,
are prepared, compounded, repackaged, dispensed, stored, sold or used for nuclear
medicine procedures. The term “nuclear pharmacy” does not include the nuclear medicine
facilities of hospitals or clinics where radiopharmaceuticals are compounded or dispensed to
patients under the supervision of a licensed physician, authorized by the Nuclear
Regulatory Commission or Agreement State regulations. Nothing in this rule shall be
construed as requiring a licensed clinical laboratory, which is also licensed by the Nuclear
Regulatory Commission or Agreement State to handle radioactive materials, to obtain the
services of a nuclear pharmacist, or to have a pharmacy permit, unless the laboratory is engaged
in the commercial sale or resale of radiopharmaceuticals.

(J) “Nuclear pharmacy technician” means a person who has successfully completed a
nuclear pharmacy technician training program provided by an accredited college program or meets the American Pharmacist’s Association’s (APhA) Guidelines for Nuclear Pharmacy Technician Training Program or an equivalent company sponsored program that meets APhA guidelines for nuclear pharmacy technician training.

(K) “Preparing” of radiopharmaceuticals means the addition of a radioactive substance, or the use of a radioactive substance in preparation of a single-dose or multiple-dose medication, pursuant to the prescription drug order/contingency prescription drug order. Such preparing of radiopharmaceuticals includes, but is not limited to, loading and eluting of radionuclide generators, using manufactured reagent kits to prepare radiopharmaceuticals, preparing reagent kits, aliquoting reagents and conducting quality control tests of radiopharmaceuticals.

(L) “Prescription drug order” means a prescription drug order issued for a specific patient for a diagnostic or therapeutic purpose.

(M) “Quality control testing” means, but not limited to, the performance of appropriate chemical, biological, physical, radiochemical, and radionuclidic purity tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(N) “Quality assurance procedures” means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(O) “Radiopharmaceutical” means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term “radiopharmaceutical” also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(P) “Radiopharmaceutical services” means, but not limited to, the procurement, storage, handling, compounding, preparation, repackaging, labeling, quality control testing, dispensing, delivery, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs; the participation in radiopharmaceutical selection and radiopharmaceutical utilization review, and also includes quality assurance procedures, radiological healthcare activities, any consulting activities associated with the use of radiopharmaceuticals, and any other activities required for provision of radiopharmaceutical care; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(Q) “Restricted area” means an area within the pharmacy that is secured from the Controlled Access Area and to which access is limited for the purpose of protecting individuals against exposure to radiation and radioactive materials.

(R) “Therapeutic prescription drug order” means a radioactive prescription drug issued for a specific patient for a therapeutic purpose.

(S) “Unit dose container” (e.g., shield or “pig”) means a container designed to hold doses of radiopharmaceutical agents and to prevent or minimize/reduce the emission of radiation or radioactive materials by using appropriate shielding materials.
(2) General Requirements for Pharmacists/Pharmacies Providing Radiopharmaceutical Services.

(A) No person may receive, acquire, possess, prepare, compound, dispense, repackage, transfer, dispose or manufacture for sale or resale any radiopharmaceutical except in accordance with the provisions of this rule and the conditions of rules and regulations promulgated by the Nuclear Regulatory Commission or applicable Agreement State.

(B) Nuclear Pharmacies shall post, in a conspicuous area of the pharmacy, a copy of the current registration with the Board of Pharmacy and a copy of the most current U.S. NRC or applicable Agreement State license which details a listing of its authorized nuclear pharmacists. A reference to its specific location within the pharmacy is acceptable.

(C) A Nuclear Pharmacy must have on file a copy of the current radioactive materials license for the licensed facility requesting any radiopharmaceutical before the radioactive drug is permitted to be dispensed to that facility. The radiopharmaceutical may only be delivered to the authorized addresses or locations listed in, or temporary job sites as authorized by, the NRC/Agreement State license. The authorized physician ordering radiopharmaceuticals is hereby recognized as the patient’s authorized designee for delivery purposes. This section is an exemption for Class E pharmacies to 20 CSR 2220-2.013(2) Prescription Delivery Requirements, which details authorized delivery sites.

(D) Nuclear pharmacies shall comply with any applicable requirements of other governing agencies regarding its daily operations and the disposal of any biohazardous medical waste.

(E) Any reusable unit dose container that is returned shall be considered to be contaminated. No pharmacy shall utilize a reusable unit dose container for radioactive doses without either an effective process to decontaminate the container of biohazardous substances or an effective mechanism to avoid contamination of the container. No pharmacy may reuse a unit dose container that remains contaminated with blood or other biohazardous substances.

(F) Appropriately labeled and, when required shielded, disposal containers shall be used for radioactive and biohazardous waste from the preparation or the return of radiopharmaceuticals. Disposal of biohazardous waste shall comply with all applicable local, state and federal requirements.

(G) A Class E pharmacy may accept returns and waste as authorized by the NRC/Agreement State regulations.

(3) Permits. Any pharmacy providing radiopharmaceutical services must obtain a Class-E radiopharmaceutical permit from the Board. Nuclear pharmacies preparing, compounding or repackaging sterile preparations must have Class H Sterile Product Compounding on their permit.

(A) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs, an authorized nuclear pharmacist. All personnel performing tasks in the preparation and dispensing of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of an authorized nuclear pharmacist. The pharmacist-in-charge shall be an authorized nuclear pharmacist and be responsible for all operations of the pharmacy.

(B) The permit to operate a nuclear pharmacy is effective so long as the pharmacy also holds a current Nuclear Regulatory Commission and/or Agreement State radioactive materials license. Copies of the most recent regulatory inspection reports shall be made available upon request to the board for inspection.
(C) The nuclear pharmacist-in-charge shall notify the Board of Pharmacy by letter of the outcome of any hearings under state or federal laws or regulations governing radioactive materials involving or against the pharmacy location licensed by the Board. Notification must be within thirty days of the date of the outcome.

(4) Space, Security, Record Keeping and Equipment.
   (A) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services provided and as required by the Nuclear Regulatory Commission or Agreement State radioactive materials license or as required by 20 CSR 2220-2.200 Sterile Compounding, 20 CSR 2220-2.400 Compounding Standards of Practice or other applicable rules of the Board. Radionuclide generators shall be stored and operated in an ISO 8 or better classified area. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:
      1. Radiopharmaceutical nonsterile and sterile preparation/dispensing area;
      2. Radioactive material shipping/receiving area;
      3. Radioactive material storage area; and
      4. Radioactive waste decay area.
   (B) The nuclear pharmacy restricted area shall be secured against unauthorized personnel and must be totally enclosed and lockable.
   (C) Nuclear pharmacies shall maintain records of acquisition, inventory, preparing, compounding, dispensing, distribution, and disposition of all radioactive drugs and other radioactive materials in accordance with State Board of Pharmacy, and Nuclear Regulatory Commission or Agreement State rules/requirements.
   (D) Nuclear pharmacies shall prepare, compound, repackage, and dispense radiopharmaceuticals in accordance with accepted standards of nuclear pharmacy practice and in compliance with 20 CSR 2220-2.200 Sterile Compounding and 20 CSR 2220-2.400 Compounding Standards of Practice. Appropriate safety and containment techniques for preparing, repackaging, and compounding radiopharmaceuticals shall be used in conjunction with the aseptic techniques required for sterile preparations. Only authorized nuclear pharmacists, intern pharmacists, and nuclear pharmacy technicians may prepare, compound, repackage or dispense radiopharmaceuticals.
   (E) Unless required by other rule or applicable law, all records required by this rule must be maintained for two (2) years and must be made available to the board or its representative upon request.

(5) Dispensing, Packaging, Labeling.
   (A) A radiopharmaceutical shall be dispensed only to a practitioner or facility authorized by the Nuclear Regulatory Commission or an Agreement State to possess, use and administer such drug for patient use or nonclinical applications, provided that a radiopharmaceutical may be transferred to a person who is authorized to possess the drug in accordance with the regulations of the NRC/Agreement State. A radiopharmaceutical shall not be dispensed directly to a patient. A nuclear pharmacy may distribute radionuclide elutions to other authorized users to meet a drug shortage.
   (B) The amount of radioactivity shall be determined by dose calibrator, appropriate radiometric methods or decay calculation methods for each individual dose immediately prior to dispensing.
(C) Radiopharmaceuticals are to be dispensed only upon a non-refillable prescription drug order or a contingency prescription drug order from a practitioner or facility authorized by the Nuclear Regulatory Commission or Agreement State to possess, use and administer radiopharmaceuticals or the practitioner’s/facility’s designated agent. The prescription drug order/contingency prescription drug order must be taken by an authorized nuclear pharmacist, intern pharmacist or nuclear pharmacy technician. Only pharmacists may receive verbal therapeutic prescription drug orders. The prescription record shall contain all information as required in 20 CSR 2220-2.018 Prescription Requirements and shall also include:

1. The date of dispensing and the calibration time of the radiopharmaceutical; and
2. The patient’s name for therapeutic prescription drug orders and blood-containing products.

(D) The unit dose container of a radiopharmaceutical to be dispensed shall be labeled with—

1. The name and address of the pharmacy;
2. The name and address of the authorized prescriber/facility where the prescription drug order/contingency prescription drug order is to be administered;
3. The date of dispensing and a unique readily retrievable identifier;
4. The standard radiation symbol;
5. The words “Caution Radioactive Material”;
6. The name of the procedure, if known;
7. The name or generally recognized and accepted abbreviation of the radiopharmaceutical, radionuclide and chemical form;
8. The requested amount of radioactivity at the calibration date and time;
9. The radiopharmaceutical beyond-use date;
10. The quantity dispensed;
11. If applicable, Molybdenum-99 content to United States Pharmacopoeia (USP) limits of <0.15uCi Mo-99 per 1mCi Tc-99m at time of administration or product expiration; and
12. The patient name or the words “Physician’s Use Only,” “Contingency Prescription Drug Order” or “Per Physician’s Order” or similar wording in the absence of a patient name. If no patient name is used, the pharmacy must be able to retrieve the name of the patient from the authorized prescriber/facility within 3 days if requested. When the prescription is for a therapeutic or blood-containing radiopharmaceutical, the patient name shall appear on the label.

(E) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with—:

1. The standard radiation symbol;
2. The words “Caution Radioactive Material”;
3. The identity of the radiopharmaceutical;
4. The unique readily retrievable identifier of the radiopharmaceutical; and
5. The patient’s name, if known or the words “Physician’s Use Only” or “Per Physician’s Order” or similar wording in the absence of a patient name.

(F) Radiopharmaceuticals approved by the United States Food and Drug Administration
are not subject to the unit dose container labeling requirements in subsection (D) or the radiometric measurement requirements of this rule if the nuclear pharmacy does not process the radioactive drugs in any manner nor violate the original manufacturer product packaging/labeling.

(6) Reference Manuals. Each nuclear pharmacy shall have a current copy of, or electronic access to:

(A) Applicable reference materials commensurate with the scope of services provided;

(B) 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; and

(C) Agreement State and/or NRC regulations governing the safe storage, handling, use, dispensing, transport and disposal of radioactive material, including but not limited to Title 10 and Title 49 of the United States Code of Federal Regulations.

(7) Special Conditions:

(A) To comply with NRC exposure guidelines of keeping radiation exposure as low as reasonably achievable (ALARA), the required pharmacist verification of the preparation shall be deemed satisfied if a pharmacist has previously verified the correct ingredients and calculations. Additionally, a pharmacist must verify the accuracy of the prescription/drug order information used and the label information prior to dispensing.

(B) At its discretion, for a pharmacy preparing, compounding, repackaging, or dispensing radiopharmaceuticals the Board may grant an exemption to regulation requirements that do not pertain to the practice of nuclear pharmacy for a time period designated by the Board if such exemption is not contrary to other 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 any proposed procedures or safeguards for protecting the public safety, health or welfare if the exemption is approved. If deemed appropriate, the Board may grant an exemption to all nuclear pharmacies based on one pharmacy’s request.
#5. Revisions to 20 CSR 2220-2.400 (Compounding Standards of Practice)
- Update on Missouri Veterinary Board Meeting
- Draft Rule
20 CSR 2220-2.400 Compounding Standards of Practice

PURPOSE: This rule defines compounding and establishes guidelines for the compounding of drugs.

(7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:

1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;

2. Date of compounding;

3. Identity of the compounding pharmacist;

4. A listing of the drug products/ingredients and their amounts by weight or volume;

5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;

6. The identity of the source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and

7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

(B) Information related to and the methods of compounding shall be available upon request.

(C) Pharmacists may compound drugs in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely with an established pharmacist/patient/prescriber relationship.

1. The compounding of drug products in anticipation of receiving prescriptions without an appropriate history of such prescriptions on file or a documented need, shall be considered manufacturing instead of compounding of the drug(s) involved. Limited quantities, for purposes of this rule, are further defined as an amount of batched product that represents a three (3)-month supply.
2. Creams, ointments, lotions, liniments or other compounded products intended for external
use may be batched in the same manner as provided for in paragraph (5)(C)(1) of this rule that
represents a one (1)-year supply.
(D) Any excess compounded products shall be stored and accounted for under conditions
dictated by its composition and stability characteristics to insure its strength, quality and purity.
Excess product shall be labeled with the name of the drug(s), an in-house lot number and beyond-
use date.
(E) Records as outlined in this rule shall be retained and made readily retrievable for inspection
for two (2) years from the date of compounding.
(F) The actual name of each active or therapeutic ingredient contained in a compound shall be
listed on the container of any product provided to a consumer.

(12) Except as provided by law, pharmacist[s] shall not offer or provide compounded [drug
products]preparations to other pharmacies, practitioners or [commercial] entities for subsequent
dispensing, distribution, resale, or administration, except in the course of professional practice for
a prescriber to administer to an individual patient by a prescription dispensed by the pharmacy. A
pharmacist or pharmacy may advertise or otherwise provide information concerning the provision
of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by
making specific claims about compounded [products]preparations.

(13) Pharmacies may provide non-patient-specific compounded preparations for veterinary use to
a Missouri-licensed veterinarian to administer and dispense to the veterinarian’s animal patients,
provided the following:
(A) The preparation container is labeled with:
1. Pharmacy name, address, and telephone number;
2. Date of distribution
3. Veterinarian’s name
4. Preparation name, strength, dosage form, and quantity;
5. Name of each active or therapeutic ingredient included in the preparation;
6. Preparation lot/batch number;
7. Preparation beyond-use date; and
(B) The pharmacy maintains a record of the distribution to the veterinarian;
(C) The pharmacy can retrieve distribution records by specific veterinarian, if requested;
(D) In lieu of (7)(A)(7), the veterinarian’s name may be recorded on the compounding log;
and
(E) The pharmacy complies with all applicable controlled substance laws and regulations.
In addition to the requirements outlined in this rule, all standards and requirements as outlined in 4 CSR 220-2.200 Sterile Pharmaceuticals must be adhered to whenever compounding involves the need for aseptic procedures or requires the use of or results in an intended sterile pharmaceutical product.

20 CSR 2220-2.400 Compounding Standards of Practice

PURPOSE: This rule defines compounding and establishes guidelines for the compounding of drugs.

(1) Compounding is defined as the preparation, incorporation, mixing and packaging or labeling of a drug or device as the result of a prescriber’s prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding may also be defined as the preparation, incorporation, mixing and packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.

(2) Manufacturing is defined as the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices.

(3) Batch compounded product is defined as a product compounded in advance of receipt of a prescription or a product compounded in a supply that will be used on more than one (1) dispensing to a patient or patients or any product compounded in excess of the filling of an individual prescription. A batch is a specific quantity of product compounded in a single, discrete process, by the same individuals, carried out during one (1) limited time period.

(4) 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.

(5) Compounding Area and Equipment Requirements.

(A) The area(s) used for the compounding of drugs shall be maintained in a sanitary condition and shall be free of infestation by insects, rodents and other vermin. Trash shall be held and disposed of in a timely and sanitary manner.

(B) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.
(C) Equipment used in the compounding of drug products shall be of appropriate design, adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that contact ingredients, in-process materials or drug products shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired.

(6) Proper controls shall be maintained over drug products/ingredients, containers and container closures.

(A) Bulk drugs and other materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(B) Pharmacists shall only receive, store or use drug substances for compounding that have been made and/or distributed by Missouri licensed/registered drug distributors.

(C) Pharmacists shall only use nondrug substances for compounding that are free of any contaminants and which maintain full potency.

(D) Drug products/ingredients, containers and container closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination.

(E) Drug product/ingredient containers and container closures shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the compounded drug beyond the desired result. Container systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.

(7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:

1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;

2. Date of compounding;

3. Identity of the compounding pharmacist;

4. A listing of the drug products/ingredients and their amounts by weight or volume;

5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;

6. The identity of the source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and

7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

(B) Information related to and the methods of compounding shall be available upon request.

(C) Pharmacists may compound drugs in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely with an established pharmacist/patient/prescriber relationship.
1. The compounding of drug products in anticipation of receiving prescriptions without an appropriate history of such prescriptions on file or a documented need, shall be considered manufacturing instead of compounding of the drug(s) involved. Limited quantities, for purposes of this rule, are further defined as an amount of batched product that represents a three (3)-month supply.

2. Creams, ointments, lotions, liniments or other compounded products intended for external use may be batched in the same manner as provided for in paragraph (5)(7)(C)1. of this rule that represents a one (1)-year supply.

(D) Any excess compounded products shall be stored and accounted for under conditions dictated by its composition and stability characteristics to insure its strength, quality and purity. Excess product shall be labeled with the name of the drug(s), an in-house lot number and beyond-use date.

(E) Records as outlined in this rule shall be retained and made readily retrievable for inspection for two (2) years from the date of compounding.

(F) The actual name of each active or therapeutic ingredient contained in a compound shall be listed on the container of any product provided to a consumer.

(8) Management of Compounding.

(A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been prepared, labeled, controlled, stored, dispensed and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:

1. Personnel are capable and qualified to perform their assigned duties;

2. Ingredients used in compounding have their expected identity, quality and purity. Drug components must meet compendial standards or maintain a certificate of analysis on file when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed;

3. Reasonable assurance that processes are always carried out as intended or specified;

4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors; and

5. All finished products, as a condition of release, must be individually inspected for evidence of visible particulates or other foreign matter and for container-closure integrity and any other apparent visual defects.

(B) The pharmacy is responsible for developing a drug monitoring system for compounded products. The outcome monitoring system shall provide readily retrievable information suitable for the evaluation of the quality of pharmaceutical services. This shall include but not be limited to reported infection rates, incidence of adverse drug reactions, incidence of recalls and complaints from prescribers or clients.

(C) A recall must be initiated when a product is deemed to be misbranded or adulterated. 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.

1. In cases where the compounded product has the potential to harm the patient, the same recall notification, as provided for in this subsection, shall be provided to all patients that have received the recalled compounded product(s).

2. Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days.
(9) Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound.

(10) Any alteration, change or modification to the contents of a commercially manufactured over-the-counter product shall require a prescription or prescription drug order from an authorized prescriber. The compounding of any drug product to be sold without a prescription is prohibited.

(11) Any person shown at any time, either by medical examination or pharmacist determination, to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with drug products/ingredients, drug product containers, container closures and in-process materials, until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products being compounded.

(12) Except as provided by law, pharmacists shall not offer or provide compounded drug products to other pharmacies, practitioners or commercial entities for subsequent dispensing, distribution, resale, or administration, except in the course of professional practice for a prescriber to administer to an individual patient by a prescription dispensed by the pharmacy. A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by making specific claims about compounded drug preparations.

(13) Pharmacies may provide non-patient-specific compounded preparations for veterinary use to a Missouri-licensed veterinarian to administer and dispense to the veterinarian’s animal patients, provided the following:

(A) The preparation container is labeled with:
   1. Pharmacy name, address, and telephone number;
   2. Date of distribution
   3. Veterinarian’s name
   4. Preparation name, strength, dosage form, and quantity;
   5. Name of each active or therapeutic ingredient included in the preparation;
   6. Preparation lot/batch number;
   7. Preparation beyond-use date; and

(B) The pharmacy maintains a record of the distribution to the veterinarian;

(C) The pharmacy can retrieve distribution records by specific veterinarian, if requested;

(D) In lieu of (7)(A)7., the veterinarian’s name may be recorded on the compounding log; and

(E) The pharmacy complies with all applicable controlled substance laws and regulations.
In addition to the requirements outlined in this rule, all standards and requirements as outlined in [4 CSR 220-2.200][20 CSR 2220-2.200] Sterile Pharmaceuticals must be adhered to whenever compounding involves the need for aseptic procedures or requires the use of or results in an intended sterile pharmaceutical product.

(3) Dispensed Drug Labeling

(H) A veterinarian may only dispense up to a seven (7) day supply to a client from an office stock compounded preparation provided by a pharmacy. A prescription must be issued to continue treatment beyond seven (7) days.
#6. **2019 Legislation**
- HB 487 (Contraceptives)
- HB 667 (Foreign Distributors)
- HB 727 (Dispensing on Hospital Discharge)
- SB 127 (Importation Study)
- SB 274 (Pharmacy Pilot Projects)
- SB 275 (Dentist Prescribing)
- SB 309 (Tobacco Cessation)
- Draft Pharmacist Scope of Practice
- Board Legislation
AN ACT

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

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

Section A. Section 338.010, RSMo, is repealed and three new sections enacted in lieu thereof, to be known as sections 338.010, 338.720, and 376.1238, to read as follows:

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

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in bold-face type in the above bill is proposed language.
contraceptives under section 338.720; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

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

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

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

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

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

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy
services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

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

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

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

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

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

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

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

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

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

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

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

2. A pharmacist may prescribe and dispense self-administered oral hormonal
contraceptives to a person who is eighteen years of age or older, regardless of whether the
person has evidence of a previous prescription from a primary care practitioner or
women's health care practitioner for a self-administered oral hormonal contraceptive.

3. The board of pharmacy shall adopt rules, in consultation with the board of
registration for the healing arts, board of nursing, and department of health and senior
services, and in consideration of guidelines established by the American Congress of
Obstetricians and Gynecologists, to establish standard procedures for the prescribing of
self-administered oral hormonal contraceptives by pharmacists. The board of pharmacy
shall adopt rules and regulations to implement the provisions of this section. Any rule or
portion of a rule, as that term is defined in section 536.010, that is created under the
authority delegated in this section shall become effective only if it complies with and is
subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This
section and chapter 536 are nonseverable, and if any of the powers vested with the general
assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove
and annul a rule are subsequently held unconstitutional, then the grant of rulemaking
authority and any rule proposed or adopted after August 28, 2019, shall be invalid and void.

4. The rules adopted under this section shall require a pharmacist to:
   (1) Complete a training program approved by the board of pharmacy that is related to prescribing self-administered oral hormonal contraceptives;
   (2) Provide a self-screening risk assessment tool that the patient shall use prior to the pharmacist's prescribing the self-administered oral hormonal contraceptive;
   (3) Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and dispensing the self-administered oral hormonal contraceptive;
   (4) Provide the patient with a written record of the self-administered oral hormonal contraceptive prescribed and dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and
   (5) Dispense the self-administered oral hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

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

376.1238. 1. For purposes of this section, the terms "health carrier" and "health benefit plan" shall have the same meaning as defined in section 376.1350. The term "self-administered oral hormonal contraceptive" shall mean a drug composed of a combination of hormones that is approved by the Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

2. Each health carrier or health benefit plan that offers or issues health benefit plans which are delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2020, and that provides coverage for self-administered oral hormonal contraceptives shall provide coverage to reimburse a health care provider or dispensing entity for a dispensation of self-administered oral hormonal contraceptives intended to last for a three-month period for the first dispensation of the self-administered oral hormonal contraceptive to an insured.

3. The coverage required by this section shall not be subject to any greater deductible or co-payment than other similar health care services provided by the health benefit plan.

4. The provisions of this section shall not apply to a supplemental insurance policy including a life care contract, accident-only policy, specified disease policy, hospital policy providing a fixed daily benefit only, Medicare supplement policy, long-term care policy,
short-term major medical policies of six months' or less duration, or any other
supplemental policy as determined by the director of the department of insurance,
financial institutions and professional registration.
AN ACT


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


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

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

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

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

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

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

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in bold-face type in the above bill is proposed language.
(4) That the management of said pharmacy is under the supervision of either a registered pharmacist, or an owner or employee of the owner, who has at his or her place of business a registered pharmacist employed for the purpose of compounding physician’s or veterinarian’s prescriptions in the event any such prescriptions are compounded or sold;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in bold-face type in the above bill is proposed language.
(1) The medication is necessary for administration during transport of the patient;
(2) The quantity of the controlled substance sent is documented in the patient's medical record by the person sending the medication; and
(3) The pharmacy is notified that the medication was sent with the patient.

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

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

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

Section A. Chapter 192, RSMo, is amended by adding thereto one new

section, to be known as section 192.340, to read as follows:

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

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

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

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

(4) Estimate potential consumer savings attributable to importation;

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

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

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

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

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

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

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

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

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

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

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

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

3. To be approved, pilot or research projects shall be within the scope of the practice of pharmacy as defined by chapter 228, be under the supervision of a Missouri licensed pharmacist, and comply with applicable compliance and reporting as established by the board by rule, including any staff training or education requirements. Board approval shall be limited to a period of up to eighteen months, provided the board grant an additional six month extension if deemed necessary or appropriate to gather or complete research data or if deemed in the best interests of the patient. The board may rescind approval of a pilot
project at any time if deemed necessary or appropriate in the interest of patient safety.

4. The provisions of this subsection shall expire on August 28, 2023. The board shall provide a final report on approved projects and related data or findings to the general assembly on or before December 31, 2022. The name, location, approval dates, general description of and responsible pharmacist for an approved pilot or research project shall be deemed an open record.
AN ACT

To repeal section 332.361, RSMo, and to enact in lieu thereof one new section relating to prescribing authority of dentists.

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

Section A. Section 332.361, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 332.361, to read as follows:

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

(1) "Acute pain", shall have the same meaning as in section 195.010;

(2) "Long-acting or extended-release opioids", formulated in such a manner as to make the contained medicament available over an extended period of time following ingestion.

2. Any duly registered and currently licensed dentist in Missouri may write, and any pharmacist in Missouri who is currently licensed under the provisions of chapter 338 and any amendments thereto, may fill any prescription of a duly registered and currently licensed dentist in Missouri for any drug necessary or proper in the practice of dentistry, provided that no such prescription is in violation of either the Missouri or federal narcotic drug act.

[2.] 3. Any duly registered and currently licensed dentist in Missouri may possess, have under his control, prescribe, administer, dispense, or distribute a "controlled substance" as that term is defined in section 195.010 only to the extent that:

(1) The dentist possesses the requisite valid federal and state registration to distribute or dispense that class of controlled substance;

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.
(2) The dentist prescribes, administers, dispenses, or distributes the controlled substance in the course of his professional practice of dentistry, and for no other reason;

(3) A bona fide dentist-patient relationship exists; and

(4) The dentist possesses, has under his control, prescribes, administers, dispenses, or distributes the controlled substance in accord with all pertinent requirements of the federal and Missouri narcotic drug and controlled substances acts, including the keeping of records and inventories when required therein.

4. Long-acting or extended-release opioids shall not be used for the treatment of acute pain. If in the professional judgement of the dentist, a long-acting or extended-release opioid is necessary to treat the patient, the dentist shall document and explain in the patient's dental record the reason for the necessity for the long-acting or extended-release opioid.

5. Dentists shall avoid prescribing doses greater than fifty morphine milligram equivalent (MME) per day for treatment of acute pain. If in the professional judgement of the dentist, doses greater than fifty MME are necessary to treat the patient, the dentist shall document and explain in the patient's dental record the reason for the necessity for the dose greater than fifty MME. The relative potency of opioids is represented by a value assigned to individual opioids known as a morphine milligram equivalent (MME). The MME value represents how many milligrams of a particular opioid is equivalent to one milligram of morphine. The Missouri dental board shall maintain a MME conversion chart and instructions for calculating MME on its website to assist licensees with calculating MME.
FIRST REGULAR SESSION

SENATE BILL NO. 309

100TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Read 1st time January 28, 2019, and ordered printed.

ADRIANE D. CROUSE, Secretary.

AN ACT

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

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

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

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

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

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

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

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

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

7. The state board of registration for the healing arts, under section
334.125, and the state board of pharmacy, under section 338.140, shall jointly
promulgate rules regulating the use of protocols for prescription orders for
medication therapy services and administration of viral influenza vaccines. Such
rules shall require protocols to include provisions allowing for timely
communication between the pharmacist and the referring physician, and any
other patient protection provisions deemed appropriate by both boards. In order
to take effect, such rules shall be approved by a majority vote of a quorum of each
board. Neither board shall separately promulgate rules regulating the use of
protocols for prescription orders for medication therapy services and
administration of viral influenza vaccines. Any rule or portion of a rule, as that
term is defined in section 536.010, that is created under the authority delegated
in this section shall become effective only if it complies with and is subject to all
of the provisions of chapter 536 and, if applicable, section 536.028. This section
and chapter 536 are nonseverable and if any of the powers vested with the
general assembly pursuant to chapter 536 to review, to delay the effective date,
or to disapprove and annul a rule are subsequently held unconstitutional, then
the grant of rulemaking authority and any rule proposed or adopted after August
28, 2007, shall be invalid and void.

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

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

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

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

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

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

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

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

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

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

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

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

3. Any rule or portion of a rule, as that term is defined in section 536.010 that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2019, shall be invalid and void.
DRAFT PROPOSAL FROM MPA:

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

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

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

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

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication [therapeutic] therapy services.
6. This section shall not be construed to allow a pharmacist to diagnose [or independently prescribe pharmaceuticals.]

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols [for prescription orders] for medication therapy services and administration of viral [influenza] vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols [for prescription orders] for medication therapy services and administration of viral [influenza] vaccines. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

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

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

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

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

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

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

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

   (3) In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon completion, and shall display the certification in his or her pharmacy where vaccines are delivered.
13. A pharmacist shall inform the patient that the administration of the vaccine will be entered into
the ShowMeVax system, as administered by the department of health and senior services. The patient
shall attest to the inclusion of such information in the system by signing a form provided by the
pharmacist. If the patient indicates that he or she does not want such information entered into the
ShowMeVax system, the pharmacist shall provide a written report within fourteen days of
administration of a vaccine to the patient's primary health care provider, if provided by the patient,
containing:

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

with S.B. 754 merged with S.B. 808)

Prior revisions: 1929 § 13140; 1919 § 4712; 1909 § 5764
1. A physician, podiatrist, dentist, a registered optometrist certified to administer
pharmaceutical agents as provided in section 336.220, or an assistant physician in accordance with
section 334.037, [or] a physician assistant in accordance with section 334.747 or a pharmacist in
accordance with section 338.010 in good faith and in the course of his or her professional practice
only, may prescribe, administer, and dispense controlled substances or he or she may cause the
same to be administered or dispensed by an individual as authorized by statute.

2. An advanced practice registered nurse, as defined in section 335.016, but not a certified
registered nurse anesthetist as defined in subdivision (8) of section 335.016, who holds a certificate
of controlled substance prescriptive authority from the board of nursing under section 335.019 and
who is delegated the authority to prescribe controlled substances under a collaborative practice
arrangement under section 334.104 may prescribe any controlled substances listed in Schedules III,
IV, and V of section 195.017, and may have restricted authority in Schedule II. Prescriptions for
Schedule II medications prescribed by an advanced practice registered nurse who has a certificate
of controlled substance prescriptive authority are restricted to only those medications containing
hydrocodone. However, no such certified advanced practice registered nurse shall prescribe
controlled substance for his or her own self or family. Schedule III narcotic controlled substance and
Schedule II - hydrocodone prescriptions shall be limited to a one hundred twenty-hour supply without
refill.

3. A veterinarian, in good faith and in the course of the veterinarian's professional practice only, and
not for use by a human being, may prescribe, administer, and dispense controlled substances and
the veterinarian may cause them to be administered by an assistant or orderly under his or her
direction and supervision.

4. A practitioner shall not accept any portion of a controlled substance unused by a patient, for any
reason, if such practitioner did not originally dispense the drug.

5. An individual practitioner shall not prescribe or dispense a controlled substance for such
practitioner's personal use except in a medical emergency.

merged with S.B. 754, A.L. 2015 H.B. 709)
#7. Rx Cares for Missouri/Medication Destruction Request for Proposals
#8. Chapter 338, RSMo Standards/Scope of Practice Review
CHAPTER 338 SCOPE OF PRACTICE REVIEW

***Research & Development will occur between Bd. meetings***

January
- Establish Chapter 338 review standards/criteria

February*
- Group 1:
  - Identification
  - Definition

March*
- Group 1:
  - Identification
  - Definition

April*
- Group 1:
  - Research
  - Engagement

May*
- Group 1:
  - Refining

June*
- Group 1:
  - Refining
  - Validation

July*
- Group 1:
  - Validation
  - Approval

August
- Final approval for submission to Division, Dept. & GO
STATUTE/RULE ADOPTION PROCESS

Identification
- Statement of topic (What’s the issue?)
- What’s the origin?
- Who’s requesting?
- Initial prioritization
  P1- Expedited
  P2- Urgent, not critical
  P3- Important & needed
  P4- Beneficial but no immediate demand
  P5- Do not pursue now

Definition
- Identify standard
- Define parameters
- List undesirables
- Timeline/Allocation of resources

Research
- State/federal examples
- Data/Evidence-Based research
- Third-party resources
- Expert consultation
- Preferred route (statute/rule)
- Partner outreach

Engagement
- Initial public/stakeholder engagement
- Working Group/Sub-Committees (as needed)

Development
- Staff drafting
- Legal review

Refining
- Board review & editing of draft language
- Assessment Questionnaire

Validation
- Does it meet Bd. requested parameters & standards?
- Public/Stakeholder comments

Approval
- Approve rule/legislative proposal for review & approval by the Division, Dept. & Governor
GROUP 1:

<table>
<thead>
<tr>
<th>Pharmacist Scope of Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>338.010 Practice of pharmacy defined — auxiliary personnel — written protocol</td>
</tr>
<tr>
<td>338.056 Generic substitutions may be made, when, requirements — violations/penalty</td>
</tr>
<tr>
<td>338.085 Interchangeable biological products, pharmacist may dispense as substitute</td>
</tr>
<tr>
<td>338.200 Pharmacist may dispense emergency prescription, when, requirements</td>
</tr>
<tr>
<td>338.202 Maintenance medications, pharmacist may exercise professional judgment</td>
</tr>
<tr>
<td>338.210 Pharmacy defined — practice of pharmacy to be conducted at pharmacy</td>
</tr>
<tr>
<td>338.400 (Blood Clotting Therapies) Standard of care, definitions, rules</td>
</tr>
</tbody>
</table>
338.010. Practice of pharmacy defined — auxiliary personnel — written protocol required, when — nonprescription drugs — rulemaking authority — therapeutic plan requirements — veterinarian defined — additional requirements — report — ShowMeVax system, notice. — 1. The “practice of pharmacy” means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons at least seven years of age or the age recommended by the Centers for Disease Control and Prevention, whichever is higher, or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, meningitis, and viral influenza vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also
not be construed to prohibit or interfere with any legally registered practitioner of
medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the
practice of optometry in accordance with and as provided in sections 195.070 and
336.220 in the compounding, administering, prescribing, or dispensing of his or her own
prescriptions.

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

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

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

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

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

7. The state board of registration for the healing arts, under section 334.125, and
the state board of pharmacy, under section 338.140, shall jointly promulgate rules
regulating the use of protocols for prescription orders for medication therapy services
and administration of viral influenza vaccines. Such rules shall require protocols to
include provisions allowing for timely communication between the pharmacist and the
referring physician, and any other patient protection provisions deemed appropriate by
both boards. In order to take effect, such rules shall be approved by a majority vote of a
quorum of each board. Neither board shall separately promulgate rules regulating the
use of protocols for prescription orders for medication therapy services and
administration of viral influenza vaccines. Any rule or portion of a rule, as that term is
defined in section 536.010, that is created under the authority delegated in this section
shall become effective only if it complies with and is subject to all of the provisions of
chapter 536 and, if applicable, section 536.028. This section and chapter 536 are
nonseverable and if any of the powers vested with the general assembly pursuant to
chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are
subsequently held unconstitutional, then the grant of rulemaking authority and any rule
proposed or adopted after August 28, 2007, shall be invalid and void.
8. The state board of pharmacy may grant a certificate of medication therapeutic
plan authority to a licensed pharmacist who submits proof of successful completion of a
board-approved course of academic clinical study beyond a bachelor of science in
pharmacy, including but not limited to clinical assessment skills, from a nationally
accredited college or university, or a certification of equivalence issued by a nationally
recognized professional organization and approved by the board of pharmacy.
9. Any pharmacist who has received a certificate of medication therapeutic plan
authority may engage in the designing, initiating, implementing, and monitoring of a
medication therapeutic plan as defined by a prescription order from a physician that is
specific to each patient for care by a pharmacist.
10. Nothing in this section shall be construed to allow a pharmacist to make a
therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized
by the written protocol or the physician’s prescription order.
11. “Veterinarian”, “doctor of veterinary medicine”, “practitioner of veterinary
medicine”, “DVM”, “VMD”, “BVSe”, “BVMS”, “BSe (Vet Science)”, “VMB”,
“MRCVS”, or an equivalent title means a person who has received a doctor's degree in
veterinary medicine from an accredited school of veterinary medicine or holds an
Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued
by the American Veterinary Medical Association (AVMA).
12. In addition to other requirements established by the joint promulgation of rules
by the board of pharmacy and the state board of registration for the healing arts:
(1) A pharmacist shall administer vaccines by protocol in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);

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

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

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

   (1) The identity of the patient;

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

   (3) The route of administration;

   (4) The anatomic site of the administration;

   (5) The dose administered; and

   (6) The date of administration.

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

2. A pharmacist who receives a prescription for a brand name drug or biological product may select a less expensive generically equivalent or interchangeable biological product unless:
   (1) The patient requests a brand name drug or biological product; or
   (2) The prescribing practitioner indicates that substitution is prohibited or displays “brand medically necessary”, “dispense as written”, “do not substitute”, “DAW”, or words of similar import on the prescription.

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

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

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

6. Violations of this section are infractions.

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

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

(2) “Interchangeable biological product”, a biological product that the Food and Drug Administration:
   (a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. Section 262(k)(4); or
   (b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

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

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

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

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

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

(1) An interoperable electronic medical records system;

(2) An electronic prescribing technology;

(3) A pharmacy benefit management system; or

(4) A pharmacy record.

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

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

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

5. The pharmacist shall maintain records in a manner consistent with section
338.100.
6. The pharmacist shall label prescriptions in a manner consistent with section
338.059.
7. The board of pharmacy shall maintain a link on its website to the current list of all
biological products determined by the Food and Drug Administration to be
interchangeable with a specific biological product.
8. The board of pharmacy may promulgate rules for compliance with the provisions
of this section. Any rule or portion of a rule, as that term is defined in section 536.010,
that is created under the authority delegated in this section shall become effective only if
it complies with and is subject to all of the provisions of chapter 536 and, if applicable,
section 536.028. This section and chapter 536 are nonseverable and if any of the
powers vested with the general assembly pursuant to chapter 536 to review, to delay
the effective date, or to disapprove and annul a rule are subsequently held
unconstitutional, then the grant of rulemaking authority and any rule proposed or
adopted after August 28, 2016, shall be invalid and void.

(L. 2016 S.B. 875)
*338.200. Pharmacist may dispense emergency prescription, when, requirements — rulemaking authority. — 1. In the event a pharmacist is unable to obtain refill authorization from the prescriber due to death, incapacity, or when the pharmacist is unable to obtain refill authorization from the prescriber, a pharmacist may dispense an emergency supply of medication if:

(1) In the pharmacist's professional judgment, interruption of therapy might reasonably produce undesirable health consequences;

(2) The pharmacy previously dispensed or refilled a prescription from the applicable prescriber for the same patient and medication;

(3) The medication dispensed is not a controlled substance;

(4) The pharmacist informs the patient or the patient's agent either verbally, electronically, or in writing at the time of dispensing that authorization of a prescriber is required for future refills; and

(5) The pharmacist documents the emergency dispensing in the patient’s prescription record, as provided by the board by rule.

2. (1) If the pharmacist is unable to obtain refill authorization from the prescriber, the amount dispensed shall be limited to the amount determined by the pharmacist within his or her professional judgment as needed for the emergency period, provided the amount dispensed shall not exceed a seven-day supply.

(2) In the event of prescriber death or incapacity or inability of the prescriber to provide medical services, the amount dispensed shall not exceed a thirty-day supply.

3. Pharmacists or permit holders dispensing an emergency supply pursuant to this section shall promptly notify the prescriber or the prescriber’s office of the emergency dispensing, as required by the board by rule.

4. An emergency supply may not be dispensed pursuant to this section if the pharmacist has knowledge that the prescriber has otherwise prohibited or restricted emergency dispensing for the applicable patient.

5. The determination to dispense an emergency supply of medication under this section shall only be made by a pharmacist licensed by the board.

6. The board shall promulgate rules to implement the provisions of this section. Any
rule or portion of a rule, as that term is defined in section 536.010, that is created under
the authority delegated in this section shall become effective only if it complies with and
is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This
section and chapter 536 are nonseverable and if any of the powers vested with the
general assembly pursuant to chapter 536 to review, to delay the effective date, or to
disapprove and annul a rule are subsequently held unconstitutional, then the grant of
rulemaking authority and any rule proposed or adopted after August 28, 2013, shall be
invalid and void.

(L. 2013 H.B. 315, A.L 2016 S.B. 608 merged with S.B. 635)

Effective 8-28-16 (S.B. 635); *10-14-16 (S.B. 608), see § 21.250

*S.B. 608 was vetoed July 5, 2016. The veto was overridden on September 14, 2016.
338.202. **Maintenance medications, pharmacist may exercise professional judgment on quantity dispensed, when.** — 1. Notwithstanding any other provision of law to the contrary, unless the prescriber has specified on the prescription that dispensing a prescription for a maintenance medication in an initial amount followed by periodic refills is medically necessary, a pharmacist may exercise his or her professional judgment to dispense varying quantities of maintenance medication per fill, up to the total number of dosage units as authorized by the prescriber on the original prescription, including any refills. Dispensing of the maintenance medication based on refills authorized by the physician or prescriber on the prescription shall be limited to no more than a ninety-day supply of the medication, and the maintenance medication shall have been previously prescribed to the patient for at least a three-month period. The supply limitations provided in this subsection shall not apply if the prescription is issued by a practitioner located in another state according to and in compliance with the applicable laws of that state and the United States or dispensed to a patient who is a member of the United States Armed Forces serving outside the United States.

2. For the purposes of this section, **“maintenance medication”** is and means a medication prescribed for chronic long-term conditions and that is taken on a regular, recurring basis; except that, it shall not include controlled substances, as defined in and under section 195.010.

338.210. Pharmacy defined — practice of pharmacy to be conducted at
pharmacy location — rulemaking authority. — 1. Pharmacy refers to any location
where the practice of pharmacy occurs or such activities are offered or provided by a
pharmacist or another acting under the supervision and authority of a pharmacist,
including every premises or other place:
   (1) Where the practice of pharmacy is offered or conducted;
   (2) Where drugs, chemicals, medicines, any legend drugs under 21 U.S.C. Section
353, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered
for sale at retail;
   (3) Where the words “pharmacist”, “apothecary”, “drugstore”, “drugs”, and any other
symbols, words or phrases of similar meaning or understanding are used in any form to
advertise retail products or services;
   (4) Where patient records or other information is maintained for the purpose of
engaging or offering to engage in the practice of pharmacy or to comply with any
relevant laws regulating the acquisition, possession, handling, transfer, sale or
destruction of drugs, chemicals, medicines, prescriptions or poisons.
2. All activity or conduct involving the practice of pharmacy as it relates to an
identifiable prescription or drug order shall occur at the pharmacy location where such
identifiable prescription or drug order is first presented by the patient or the patient’s
authorized agent for preparation or dispensing, unless otherwise expressly authorized
by the board.
3. The requirements set forth in subsection 2 of this section shall not be construed
to bar the complete transfer of an identifiable prescription or drug order pursuant to a
verbal request by or the written consent of the patient or the patient’s authorized agent.
4. The board is hereby authorized to enact rules waiving the requirements of
subsection 2 of this section and establishing such terms and conditions as it deems
necessary, whereby any activities related to the preparation, dispensing or recording of
an identifiable prescription or drug order may be shared between separately licensed
facilities.
5. If a violation of this chapter or other relevant law occurs in connection with or
adjunct to the preparation or dispensing of a prescription or drug order, any permit
holder or pharmacist-in-charge at any facility participating in the preparation,
dispensing, or distribution of a prescription or drug order may be deemed liable for such
violation.

6. Nothing in this section shall be construed to supersede the provisions of section
197.100.

338.400. Standard of care, definitions, rules. — 1. As used in this section, the following terms shall mean:

(1) “Ancillary infusion equipment and supplies”, the equipment and supplies required to infuse a blood clotting therapy product into a human vein, including syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs;

(2) “Assay”, the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug;

(3) “Bleeding disorder”, a medical condition characterized by a deficiency or absence of one or more essential blood-clotting components in the human blood, including all forms of hemophilia, von Willebrand’s disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting;

(4) “Blood clotting product”, a medicine approved for distribution by the federal Food and Drug Administration that is used for the treatment and prevention of symptoms associated with bleeding disorders, including but not limited to recombinant Factor VII, recombinant-activated Factor VIIa, recombinant Factor VIII, plasma-derived Factor VIII, recombinant Factor IX, plasma-derived Factor IX, von Willebrand factor products, bypass products for patients with inhibitors, prothrombin complex concentrates; and activated prothrombin complex concentrates;

(5) “Home nursing services”, specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products;

(6) “Home use”, infusion or other use of a blood clotting product in a place other than a hemophilia treatment center, hospital, emergency room, physician’s office, outpatient facility, or clinic;

(7) “Pharmacy”, an entity engaged in practice of pharmacy as defined in section 338.010 that provides patients with blood clotting products and ancillary infusion equipment and supplies.

2. The Missouri state board of pharmacy shall promulgate rules governing the
standard of care for pharmacies dispensing blood clotting therapies. Such rules shall include, when feasible, the standards established by the medical advisory committees of the patient groups representing the hemophilia and von Willebrand diseases, including but not limited to Recommendation 188 of the National Hemophilia Foundation's Medical and Scientific Advisory Council. Such rules shall include safeguards to ensure the pharmacy:

1. Has the ability to obtain and fill a physician prescription as written of all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges of low, medium, and high, as applicable, and vial sizes, including products manufactured from human plasma and those manufactured from recombinant technology techniques, provided manufacturer supply exists and payer authorization is obtained;

2. Provides for the shipment of prescribed blood clotting products to the patient within two business days or less for established patients and three business days or less for new patients in nonemergency situations;

3. Provides established patients with access to blood clotting products within twelve hours of notification by the physician of the patient's emergent need for blood clotting products;

4. Provides all ancillary infusion equipment and supplies necessary for established patients for administration of blood clotting products;

5. Has a pharmacist available twenty-four hours a day, seven days a week, every day of the year, either onsite or on call, to fill prescriptions for blood clotting products;

6. Provides patients who have received blood clotting products with a designated contact telephone number for reporting problems with a delivery or product;

7. Provides patients with notification of recalls and withdrawals of blood clotting products and ancillary infusion equipment within twenty-four hours of receipt of the notification; and

8. Provides containers for the disposal of hazardous waste, and provides patients with instructions on the proper collection, removal, and disposal of hazardous waste under state and federal law.
3. Notwithstanding the provisions of subsection 2 of this section, pharmacies and pharmacists shall exercise that degree of skill and learning ordinarily exercised by members of their profession in the dispensing and distributing of blood clotting products.

(L. 2011 H.B. 552)

*Word “provide” appears in original rolls.*
#9. **Special Sites**
- Cox Health Center Steeplechase
- Eli Lilly
- Pharm to Farm
- Providence Family Medicine
- Quentin N. Burdick Memorial Health Center
- Strand Clinical Technologies
- Tria Health
- UMKC School of Pharmacy at MSU
- Winslow Indian Health
#10. **FY18 Annual Report**
- Draft Annual Report

**STAFF NOTES**
#11 20 CSR 2220-8.040 Standards of Operation (Drug Outsourcers)

- Final Order of Rulemaking

-
PROPOSED RULE

ORDER OF RULEMAKING

By the authority vested in the Missouri Board of Pharmacy under sections 338.140, 338.150, 338.280 and 338.350, RSMo 2016 and sections 338.315, 338.330, 338.333, 338.337 and 338.340, RSMo Supp. 2018, the Board of Pharmacy adopts a rule as follows:

20 CSR 2220-8.040 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the Missouri Register on January 2, 2019 (44 MoReg. 115-116). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the Code of State Regulations.

SUMMARY OF COMMENTS: The Board received one (1) comment in response to the proposed rule.

COMMENT # 1: A Board inspector recommended the rule require the supervising pharmacist for a drug outsourcer to be a Missouri licensed pharmacist.

RESPONSE AND EXPLANATION OF CHANGE: The Board agrees with the change given the supervising pharmacist activities will be performed in the state of Missouri. Additionally, Missouri licensure may be legally required by Chapter 338, RSMo.

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

(2) No drug outsourcer license will be issued unless the facility is under the direct supervision of a Missouri licensed pharmacist who has been designated with the board and who will be responsible for facility operations and ensuring compliance with state and federal law. The pharmacist must hold a current and active pharmacist license issued by Missouri or another U.S. state territory.