Meeting Notice
Missouri Board of Pharmacy
July 12-13, 2017 (Wednesday-Thursday)
Courtyard Columbia
3301 Lemone Industrial Blvd.
Columbia, Missouri

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0093 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

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

The Board may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.
JULY 12-13, 2017

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

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

#A2. Roll Call Christina Lindsay, PharmD, President

#A3. Agenda Additions/Corrections

#A4. PUBLIC HEARING ON BOARD RULES PURSUANT TO EXECUTIVE ORDER 17-03 (8:30 A.M.)
   • In January 2017, Governor Eric R. Greitens issued Executive Order 17-03 which requires state agencies to review all rules under their jurisdiction. As part of the review, state agencies are required to hold at least two (2) public hearings to allow citizens and businesses to identify regulations that are ineffective, unnecessary or unduly burdensome. In compliance with Executive Order 17-03, the Board will be accepting public comments at the July meeting on any of the Board rules. Public comments may be limited to three (3) minutes per participant to accommodate all attendees. Small businesses are encouraged to participate.

#A5. 2018 Proposed Legislation
   • Pharmacy Technician Standards/Registration
   • Licensing of Third Party Logistics Providers/Drug Outsourcers
   • Pharmacist Continuing Education
   • Charitable Pharmacy
   • Civil Penalties

#A6. 2020 Rule Review
(In addition to the rule review required by Executive Order 17-03, the Board will also review the following individual rules. Public comment will be limited to three (3) minutes per participant)

- Rule Review Calendar
- 20 CSR 2220-2.400 (Compounding Standards of Practice)
- 20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operation)
- 20 CSR 2220-2.600 (Standards of Operation for a Class F: Renal Dialysis Pharmacy)
- 20 CSR 2220-2.675 (Standards of Operation/Licensure for Class-L Veterinary Pharmacies)
- 20 CSR 2220-6.100 (Pharmacy Standards for Dispensing Blood-Clotting Products)

#A7. Draft Rules Under Review

- 20 CSR 2220-2.010 Pharmacy Standards of Operation (Draft)
- 20 CSR 2220-2.012 Pharmacy Supervision
- 20 CSR 2220-2.025 Non-Resident Pharmacies
- 20 CSR 2220-2.090 Pharmacist-In-Charge
- 20 CSR 2220-2.950 Automated Filling Systems
- 20 CSR 2220-6.040 Administration by Medical Prescription Order  (Draft)
- 20 CSR 2220-6.050 Administration of Vaccines Per Protocol (Draft)

#A8. Approval of Minutes

#A9. Board Member Reports

#A10. General Administration Report

- Staff/Office Update
- Financial Report
- Task Force Survey
- 2017 Patient Safety Conference
- Bd. of Healing Arts Opioid Safety Conference
- 2017 Legislative Update
- Revised Board Brochures/Practice Guide
- NABP Sterile Compounding Blueprint Update
- Pending Rules

#A11. Inspection/Investigation Report

- Inspection/Investigation Updates

#A12. Hospital Advisory Committee Update

- Chairman Updates
- Update on Class-B Hospital Guidance

#A13. Sterile Compounding Committee Update
#A14. Fiscal Year 2018-2019 Strategic Plan

#A15. Discussion of Remote Technician Supervision/Remote Medication Verification

#A16. STLCoP and UMKC College of Pharmacy
   • STLCoP Site Listing
   • STLCoP Preceptor Listing
   • UMKC Site Listing
   • UMKC Preceptor Listing
   • Future Approval of STLCoP & UMKC Preceptor/Pharmacy Site Lists

#A17. Applications for Intern Training Special Site/Non-Pharmacist Preceptor
   • Ascension
   • Faith Community Health Clinic
   • Missouri Pharmacy Association
   • Moberly Regional Medical Center Pharmacy
   • Pharmacie de la Tour
   • Rusk Rehabilitation Center
   • US Food and Drug Administration, Silver Spring, MD
   • Washington University

#A18. Election of Officers

#A19. Legal Contract Approval

#A20. Gerald Cipponeri Disciplinary Hearing, #042806, #2014-002902

    Thursday, July 13, 2017
    10:30 A.M. – 1st case

#A21. Board Disciplinary Report (For Informational Purposes Only)

#A22. Board Licensing Statistics (For Informational Purposes Only)

#A23. The Board may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (5), (7), and (14) and under Section 324.001.8, and .9 RSMo. The Board will return to open session at the conclusion of discussion of closed session items.

#A24. Adjournment
#A5. 2018 Proposed Legislation

- Pharmacy Technician Standards/Registration
- Licensing of Third Party Logistics Providers/Drug Outsourcers
- Pharmacist Continuing Education
- Charitable Pharmacy
- Civil Penalties
Section 338.013  1. Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy technician. Such applicant shall be, at a minimum, legal working age and shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

1. Definitions.
(A) Pharmacy Technician Trainee- Registered pharmacy support staff or a registered pharmacy technician who is in training for a pharmacy technician or an advanced pharmacy technician registration.
(B) Registered Pharmacy Support Staff- An individual with physical access to a pharmacy, or who has the authority or ability to order legend medication for pharmacy use, but does not assist or support a pharmacist in the practice of pharmacy. Registered Pharmacy Support Staff shall not include individuals with incidental access to the pharmacy while under the direct supervision of a board licensee or registrant, as defined by the Board by rule.
(C) Registered Pharmacy Technician: An individual who assists or supports a pharmacist in the practice of pharmacy, including, but not limited to an individual engaged in dispensing or filling of prescriptions or medical orders.
(D) Registered Advanced Pharmacy Technician- An individual who assists or supports a pharmacist in the practice of pharmacy and who performs advanced
technician functions or exercises increased independence, as defined/authorized by the Board by rule. At a minimum, advanced pharmacy technician duties shall include:

1. Sterile Compounding;

2. Preparation of chemotherapy or nuclear medications or preparation of hazardous injectables; and

3. Remote pharmacy technician activity, as authorized by the Board by rule.

Pharmacy support staff, pharmacy technicians and advanced pharmacy technicians must be registered with the board. To be eligible for registration, applicants shall file an application on a form provided by the board with the appropriate fee, undergo a criminal history background check and comply with the following:

(A) Registered Pharmacy Support Staff applicants must be of legal working age;

(B) Registered Pharmacy Technician applicants must be at least sixteen (16) years old and have completed an employer based training program that includes minimum training components, as specified by the Board by rule. OR—

(B) Registered Pharmacy Technician applicants must be at least sixteen (16) years old and have completed an employer based training program, as provided by the Board by rule. At a minimum, an employer-based training program must include training in the following:

(a) Pharmacy terminology;

(b) Pharmacy calculations;

(c) Dispensing systems;

(d) Labeling requirements;

(e) Applicable state and federal pharmacy and drug laws and regulations;

(f) Record keeping and documentation;

(g) Proper handling and storage of medications, and;

(h) Pharmacy policies and procedures.

(C) Registered Advanced Pharmacy Technicians applicants must be at least sixteen (16) years old and must hold an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies or, for applicants that will be assisting in the practice of nuclear pharmacy, have
completed a nuclear pharmacy technician certificate program from a provider accredited by the Accreditation Council for Pharmacy Education or its successor.

3. Pharmacy Technician Trainees. The pharmacy shall maintain a list of all pharmacy support staff and registered pharmacy technicians designated as pharmacy technician trainees and the training start date. Once designated, the trainee may engage in registered pharmacy technician or advanced pharmacy technician functions, as authorized by the rules of the Board and the pharmacist-in-charge. A registrant may not be designated as a pharmacy technician trainee for more than one (1) year, provided the pharmacist-in-charge may grant a six (6) month extension for good cause. If training is not completed within the required one (1) year or eighteen (18) months, the registrant may not be re-designated as a trainee for a minimum of six (6) months.

24. The board may refuse to issue a certificate of registration as a pharmacy technician registration authorized by this section to an applicant that has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055. Alternately, the board may issue such person a registration, but may authorize the person to work as a pharmacy technician provided that person adheres to certain terms and conditions imposed by the board. The board shall place on the employment disqualification list the name of an applicant who the board has refused to issue a certificate of registration as a pharmacy technician, or the name of a person who the board has issued a certificate of registration as a pharmacy technician but has authorized to work under certain terms and conditions. The board shall notify the applicant of the applicant's right to file a complaint with the administrative hearing commission as provided by chapter 621.

3. If an applicant has submitted the required fee and an application for registration to the board of pharmacy, the applicant may begin performing activities authorized for the registration class once the completed application has been submitted to the board. The applicant shall keep a copy of the
submitted application on the premises where the applicant is employed. If the board refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant shall immediately cease assisting a licensed pharmacist in the practice of pharmacy performing the applicable technician activities.

4. A certificate of registration issued by the board or other proof of registration authorized by the board shall be conspicuously displayed in the pharmacy or place of business where the registrant is employed or performing registrant activities.

5. Every pharmacy technician registrant who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. The registration shall lapse and become null and void thirty days after the expiration date. To renew, registered advanced pharmacy technicians must submit proof that he/she holds a current and active certification identified in section (2)(3).

6. The board shall maintain an employment disqualification list. No person whose name appears on the employment disqualification list shall work as a pharmacy technician, pharmacy support staff registrant, registered pharmacy technician or an advanced registered pharmacy technician, except as otherwise authorized by the board. The board may authorize a person whose name appears on the employment disqualification list to work or continue to work as a pharmacy technician registrant provided the person adheres to certain terms and conditions imposed by the board.

7. The board may place on the employment disqualification list the name of a pharmacy technician registrant who has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055.

8. After an investigation and a determination has been made to place a person's name on the employment disqualification list, the board shall notify such person in writing mailed to the person's last known address:
(1) That an allegation has been made against the person, the substance of the allegation and that an investigation has been conducted which tends to substantiate the allegation;

(2) That such person's name has been added in the employment disqualification list of the board;

(3) The consequences to the person of being listed and the length of time the person's name will be on the list; and

(4) The person's right to file a complaint with the administrative hearing commission as provided in chapter 621.

9. The length of time a person's name shall remain on the disqualification list shall be determined by the board.

10. No hospital or licensed pharmacy shall knowingly employ any person whose name appears on the employee disqualification list, except that a hospital or licensed pharmacy may employ a person whose name appears on the employment disqualification list but the board has authorized to work under certain terms and conditions. Any hospital or licensed pharmacy shall report to the board any final disciplinary action taken against a pharmacy technician or the voluntary resignation of a pharmacy technician registrant against whom any complaints or reports have been made which might have led to final disciplinary action that can be a cause of action for discipline by the board as provided for in subsection 2 of section 338.055. Compliance with the foregoing sentence may be interposed as an affirmative defense by the employer. Any hospital or licensed pharmacy which reports to the board in good faith shall not be liable for civil damages.

11. Any person who holds a current and active pharmacy technician registration on or before January 1, 2019 or a later date designated by the Board, may apply to the Board for an advanced technician registration without fee. To be eligible for advanced technician registration under this subsection, the application must be accompanied by a statement from a Missouri licensed pharmacist attesting that the applicant has practiced as a pharmacy technician for a minimum of 400 hours and that such practice included...
in whole or in part, the performance of advanced technician duties, as designated by the Board by rule. Any person registered pursuant to this subsection who fails to maintain their advanced technician registration current and active shall be treated in the same manner as a new applicant and shall comply with all advanced technician registration requirements upon reapplication.

Luebbert, Jennifer

Subject: FW: BOARD 2018 RULE REVIEW

From: compliance@pr.mo.gov [mailto:compliance@pr.mo.gov]
Sent: Monday, June 26, 2017 2:05 PM
To: compliance@pr.mo.gov
Subject: BOARD 2018 RULE REVIEW

Date Received: 6/26/2017 2:04:50 PM
Rule: OTHER
Comments Filed on Behalf of: Self
Name:
Comments: Hello, I am a community pharmacist in Missouri. I would like to comment on the proposed changes to 338.013, RSMo regarding pharmacy technicians' scope of practice. In theory, it may seem like expanding the role of the pharmacy technician would allow pharmacists to focus efforts on patient care and clinical services. Realistically, I believe this would have detrimental effects to pharmacists and patients. As of right now, there are very limited reimbursement opportunities for pharmacist performed clinical services so I do not believe this would lead to more clinical services. Alternatively, I believe it would lead to less pharmacist job positions in Missouri. Furthermore, I believe this would be harmful to patients. Pharmacists are the medication experts and have the training to determine the safety of medication therapy. Allowing pharmacy technicians more of a role in dispensing will open the door for increased medication errors. Additionally, employers will see this as a way to function with an increased number of lower paid technicians and less higher paid pharmacists. Missouri does not have a required pharmacist to technician ratio so pharmacists will be responsible for a higher prescription load than ever before once again leading to more errors. As the Board of Pharmacy, it is your job to ensure the safety of patients and this proposed change will certainly lead to more medication errors and adverse medication effects. I hope that you will reconsider this change for the good of Missouri citizens. Thank you.

Address:
License #:
June 26, 2017

To: Missouri Board of Pharmacy

Care of: Kim Grinston, Executive Director

Topic: Support of Pharmacy Technician Initiative

As a past president of MSHP and board member of MPA, I write in support of the Missouri Technician Initiative as an individual consumer of pharmacy services, registered pharmacist and pharmacy educator.

I believe the Missouri Technician Working Group has done strong work that has the potential to increase patient safety in medication use. The expanded role of pharmacy technicians under appropriate supervision will allow select pharmacy personnel to practice in advance roles that will benefit the business of pharmacy and improve the care of the patient.

To ensure a safe medication environment, pharmacy must have a competent workforce. This workforce includes the maximum use of pharmacists and pharmacy support personnel. Similar to the requirement registered pharmacists have to complete a common baseline exam, pharmacy support personnel practicing in advanced roles should be held to a similar baseline competence. This baseline competence assessment must be balanced with an education curriculum and with the expected work tasks. While the baseline competence may need to be determined by state and national standards, the selection of work tasks and training necessary for these tasks can be determined by the work location pharmacist in charge. Please do not mandate rules that will increase the cost of my current pharmacy staff; please let me and the PICs to determine if advanced practice roles are appropriate for our practice environment and voluntarily engage in those tasks, the training in those tasks and the expenses necessary to train and employ those with the necessary skills.

The Missouri Board of Pharmacy has had a rich history of inclusion and broad spectrum consensus building through taskforces, working groups and advisory boards. I thank you for accepting this input.

I support the initiative to submit a request to the Governor’s office to be considered for Missouri Legislative action. Further, I support the role of the Missouri Board of Pharmacy to draft and implement rules governing the use of Pharmacy Support Personnel. I also support the role of the Department of Health to structure the practice of pharmacy personnel in the institutional and hospital settings.

I support the potential pharmacy technician legislation to be simple and not limiting. I believe the legislation should allow a progressive scope of practice, but allow the Board of Pharmacy and Dept of Health to write the specific rules for the use of pharmacy support personnel to ensure the safety of patients and safe medication use.
I support taking paced steps that include checks and balances based on patient safety and consensus among the pharmacy practitioners. Further, I support the use of pilot programs and practice programs based on applications approved by the Board of Pharmacy. Other progressive states have successfully used pilot programs and practice standards only upon approval by the Board of Pharmacy. As these pilot programs are implemented, refined and become the standard of practice; board rules can be modified to reflect the new practices that are established to be safe and to the benefit of the patient.

There is no doubt that the current practice of pharmacy is different in hospital, independent retail, chain retail, long term care, nuclear pharmacy and consulting practice. But it is still possible for pharmacy to have common practice standards with customized practice rules based on the practice environment. As a pharmacist that currently practices in different settings, I recognize the difference in definition when it comes to pharmacy tasks and activities. We, as a profession, need to continue the dialogue to learn from each other and ensure we are using common definitions and working towards the same common goals of medication safety and patient care.

Thank you for taking time to address these challenging practice standards.

Daniel H. Good, MS, RPh, FASHP

1013 W. Sycamore St. Springfield Missouri
Pharmacy technician to register with board of pharmacy, fees, application, renewal--refusal to issue, when--employee disqualification list maintained, use.

338.013. 1. Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy technician. Such applicant shall be, at a minimum, legal working age and shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter. Pharmacy technicians may engage in the following advanced technician functions subject to standards and requirements established by the Board by rule:

   a. Technology assisted final dispensing verification; and

   b. Remote pharmacy technician activities.

2. The board may refuse to issue a certificate of registration as a pharmacy technician to an applicant that has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055. Alternately, the board may issue such person a registration, but may authorize the person to work as a pharmacy technician provided that person adheres to certain terms and conditions imposed by the board. The board shall place on the employment disqualification list the name of an applicant who the board has refused to issue a certificate of registration as a pharmacy technician, or the name of a person who the board has issued a certificate of registration as a pharmacy technician but has authorized to work under certain terms and conditions. The board shall notify the
applicant of the applicant's right to file a complaint with the administrative hearing commission as provided by chapter 621.

3. If an applicant has submitted the required fee and an application for registration to the board of pharmacy, the applicant for registration as a pharmacy technician may assist a licensed pharmacist in the practice of pharmacy as defined in this chapter. The applicant shall keep a copy of the submitted application on the premises where the applicant is employed. If the board refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant shall immediately cease assisting a licensed pharmacist in the practice of pharmacy.

4. A certificate of registration issued by the board shall be conspicuously displayed in the pharmacy or place of business where the registrant is employed.

5. Every pharmacy technician who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. The registration shall lapse and become null and void thirty days after the expiration date.

6. The board shall maintain an employment disqualification list. No person whose name appears on the employment disqualification list shall work as a pharmacy technician, except as otherwise authorized by the board. The board may authorize a person whose name appears on the employment disqualification list to work or continue to work as a pharmacy technician provided the person adheres to certain terms and conditions imposed by the board.

7. The board may place on the employment disqualification list the name of a pharmacy technician who has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055.

8. After an investigation and a determination has been made to place a person's name on the employment disqualification list, the board shall notify such person in writing mailed to the person's last known address:
(1) That an allegation has been made against the person, the substance of the
allegation and that an investigation has been conducted which tends to substantiate the
allegation;

(2) That such person's name has been added in the employment disqualification list
of the board;

(3) The consequences to the person of being listed and the length of time the
person's name will be on the list; and

(4) The person's right to file a complaint with the administrative hearing commission
as provided in chapter 621.

9. The length of time a person's name shall remain on the disqualification list shall
be determined by the board.

10. No hospital or licensed pharmacy shall knowingly employ any person whose
name appears on the employee disqualification list, except that a hospital or licensed
pharmacy may employ a person whose name appears on the employment
disqualification list but the board has authorized to work under certain terms and
conditions. Any hospital or licensed pharmacy shall report to the board any final
disciplinary action taken against a pharmacy technician or the voluntary resignation of a
pharmacy technician against whom any complaints or reports have been made which
might have led to final disciplinary action that can be a cause of action for discipline by
the board as provided for in subsection 2 of section 338.055. Compliance with the
foregoing sentence may be interposed as an affirmative defense by the employer. Any
hospital or licensed pharmacy which reports to the board in good faith shall not be liable
for civil damages.

Receipt of drugs from unlicensed distributor or pharmacy, unlawful--penalty--pharmacy-to-pharmacy transfers, limit--legend drugs, inventories and records--rulemaking authority

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. 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 D 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.

Definitions.

338.330. As used in sections 338.300 to 338.370, the following terms mean:
(1) “Drug Outsourcer”: An outsourcing facility as defined by 21 USC § 353b of the federal Drug Quality and Security Act;

(2) "Legend drug":

(a) Any drug or biological product:

   a. Subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to such Section 503(b); or

   b. Required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:

      (i) "Caution: Federal law prohibits dispensing without prescription";

      (ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian";

      or

      (iii) "Rx Only";

   c. Required by any* applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use or dispensed by practitioners only; and

(b) The term "drug", "prescription drug", or "legend drug" shall not include:

   a. An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such** drug or product that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.;

   b. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; or

   c. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46;

(3) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no physical facilities located in the state;

(4) "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210, engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where such delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy;
"Wholesale drug distributor", anyone engaged in the delivery or distribution of legend drugs from any location and who is involved in the actual, constructive or attempted transfer of a drug or drug-related device in this state, other than to the ultimate consumer. This shall include, but not be limited to, drug wholesalers, repackagers and manufacturers which are engaged in the delivery or distribution of drugs in this state, with facilities located in this state or in any other state or jurisdiction. A wholesale drug distributor shall not include any common carrier or individual hired solely to transport legend drugs. Any locations where drugs are delivered on a consignment basis, as defined by the board, shall be exempt from licensure as a drug distributor, and those standards of practice required of a drug distributor but shall be open for inspection by board of pharmacy representatives as provided for in section 338.360.

"Third-party Logistics Provider", an entity that provides or coordinates warehousing, or other logistics services of a product on behalf of a drug manufacturer, wholesale distributor, or dispenser of a legend drug, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

License required, temporary licenses may be granted--out-of-state distributors, reciprocity allowed, when.

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, drug outsourcer or third party logistics provider, 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, or pharmacy distributor, drug outsourcer or third party logistics provider need not seek licensure under this section and may lawfully possess pharmaceutical drugs, if he-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 an out-of-state wholesale drug distributor or out-of-state pharmacy distributor 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, or pharmacy distributor, drug outsourcer 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, or pharmacy distributor, drug outsourcer or third party logistics provider of this state.

Out-of-state distributors, licenses required, exception.

338.337. It shall be unlawful for any out-of-state wholesale drug distributor, or out-of-state pharmacy acting as a distributor, drug outsourcer or out-of-state 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 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 out-of-state wholesale drug distributor or out-of-state pharmacy -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.

**Sale of drugs, out-of-state distributor, license required.**

338.340. No person acting as principal or agent for any out-of-state wholesale drug distributor, or 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 wholesale drug distributor or pharmacy distributor entity has obtained a license pursuant to the provisions of sections 338.330 to 338.370.
Renewal of license or permit--late renewal or failure to renew, effect--continuing education requirements--inactive license issued when--changed to active, procedure.

338.060 1. Every licensed pharmacist or permit holder who desires to continue in the practice of this profession shall, within thirty days before the license expiration date, file an application for the renewal before the license expiration date, which application shall be accompanied by the fee prescribed in sections 338.010 to 338.198.

2. If any pharmacist fails, after the expiration of the pharmacist's license, to make application to the board for its renewal, the pharmacist's name shall be removed from the register of licensed pharmacists, and such person, in order to again become registered as a licensed pharmacist, shall be required to pay all delinquent fees. Any pharmacist who fails to renew the pharmacist's license within two years of its expiration and then desires to be preregistered shall be treated in the same manner as a person who has never been licensed. Any registered pharmacist whose certificate of registration has expired while the pharmacist has been engaged in active duty with the United States Army, United States Navy, United States Air Force, the Marine Corps, Coast Guard, or any other branch of the armed services or the state militia called into the service or training of the United States of America, or in training or education under the supervision of the United States preliminary to induction into the military services may have the pharmacist's certificate of registration renewed without paying any lapse, renewal or registration fee or without passing any examination, if within one year after the termination of such service, training or education, other than by dishonorable discharge, the pharmacist furnishes the board with an affidavit to the effect that the pharmacist has been so engaged and that the pharmacist's service, training or education has terminated.

3. Except as provided in subsection 5 of this section, when applying for a renewal of the license as required by the provisions of this section, each licensed pharmacist shall submit proof
of the completion of at least fifteen-thirty hours of board-approved continuing education courses during each twelve-month biennial renewal period immediately preceding the date of the application for renewal of the license. The board shall prescribe the form to be completed. No license shall be renewed unless the holder thereof has complied with the provisions of this subsection.

4. The proof of completion of such continuing education shall be in such form as the board may require. The approved courses shall include those offered by correspondence, but the board shall approve all courses of instruction which may be used to satisfy the education requirements of subsection 3 of this section.

5. Each licensed pharmacist may, instead of submitting proof of the completion of the required continuing education courses, apply for an inactive license at the time the pharmacist makes application for the renewal of the pharmacist's license and pay the required renewal fee. An inactive license shall then be issued, and may be renewed biennially. While the inactive license is in effect the pharmacist shall not practice pharmacy. The inactive license may be changed to a regular license without other examination whenever the pharmacist submits proof of the completion of the total number of continuing education courses required for each biennial renewal period since the pharmacist was last licensed on an active basis.


Prior revisions: 1929 § 13145; 1919 § 4717; 1909 § 5769
DRAFT Language – Proposal # (Charitable Pharmacies)

Equipment required—manner of operation of pharmacy—compliance with state and federal laws required.

338.250. 1. 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 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.

2. The Board may issue a temporary charitable pharmacy permit to a Missouri licensed pharmacy or pharmacist to operate a charitable pharmacy at a specified physical location, provided a temporary charitable permit shall not be issued for more than a seven (7) day period and may not be renewed or reissued unless otherwise authorized by the Board.

3. 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, 2018, shall be invalid and void.

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

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

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

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

   (3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;
(4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

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

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

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

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

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

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

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

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

(13) Violation of any professional trust or confidence;

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

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;
(16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section 338.056, and any such substituting or changing of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional or dishonorable conduct unless a violation of section 338.056 occurs;

(17) Personal use or consumption of any controlled substance unless it is prescribed, dispensed, or administered by a health care provider who is authorized by law to do so.

3. After the filing of such complaint, the proceedings shall be conducted in accordance with the provisions of chapter 621. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the board may, singly or in combination, assess an administrative civil penalty, require satisfactory completion of a continuing professional education program as the board may specify, censure or place the person named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, or permit. The board may impose additional discipline on a licensee, registrant, or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. The additional discipline may include, singly or in combination, an administrative civil penalty, require satisfactory completion of a continuing professional education program, censure, placing the licensee, registrant, or permittee named in the complaint on additional probation on such terms and conditions as the board deems appropriate, which additional probation shall not exceed five years, or suspension for a period not to exceed three years, or revocation of the license, certificate, or permit.
4. If the board concludes that a licensee or registrant has committed an act or is engaging in a course of conduct which would be grounds for disciplinary action which constitutes a clear and present danger to the public health and safety, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the licensee's or registrant's license. Within fifteen days after service of the complaint on the licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the licensee or registrant appear to constitute a clear and present danger to the public health and safety which justify that the licensee's or registrant's license or registration be immediately restricted or suspended. The burden of proving that the actions of a licensee or registrant constitute a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

5. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the licensee's or registrant's license, such temporary authority of the board shall become final authority if there is no request by the licensee or registrant for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the licensee or registrant named in the complaint, set a date to hold a full hearing under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed by the board.

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

7. Any civil penalty imposed by the board under subsection 3 of this section shall not exceed two thousand five hundred dollars for each offense. Each day of a continued violation constitutes a separate offense, with a maximum penalty of twenty-five
thousand dollars. In determining the amount of penalty to be imposed, the Board may consider any of the following:

1. Whether the amount imposed will be a substantial deterrent to the violation;
2. The circumstances leading to the violation;
3. The severity of the violation and the risk of harm to the public;
4. The economic benefits gained by the violator as a result of noncompliance; and
5. The interest of the public.

8. Any disciplinary order imposing a civil penalty is subject to judicial review upon the filing of a petition under section 536.100 by any person subject to the penalty.

9. Failure to pay a civil penalty shall be grounds for denying, disciplining or refusing to renew or reinstate a license, registration or permit. If the penalty is not timely paid, the board may notify the attorney general. The attorney general may commence an action to recover the amount of the penalty, including reasonable attorney fees and costs. In such action, the validity and appropriateness of the final order imposing the civil penalty shall not be subject to review.

10. Penalties collected under this section shall be handled in accordance with Section 7 of Article IX of the Missouri Constitution. Such penalties shall not be considered a charitable contribution for tax purposes.
#A6. **2020 Rule Review**

*(In addition to the rule review required by Executive Order 17-03, the Board will also review the following individual rules. Public comment will be limited to three (3) minutes per participant)*

- Rule Review Calendar
- 20 CSR 2220-2.400 (Compounding Standards of Practice)
- 20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operation)
- 20 CSR 2220-2.600 (Standards of Operation for a Class F: Renal Dialysis Pharmacy)
- 20 CSR 2220-2.675 (Standards of Operation/Licensure for Class-L Veterinary Pharmacies)
- 20 CSR 2220-6.100 (Pharmacy Standards for Dispensing Blood-Clotting Products)
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)(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) Pharmacists shall not offer compounded drug products to other pharmacies, practitioners or commercial entities for subsequent resale or administration, except in the course of professional practice for a prescriber to administer to an individual patient by prescription. 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.

(13) 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.

Nuclear Pharmacy—Minimum Standards for Operation

PURPOSE: This rule defines minimum standards for the operation of nuclear pharmacies, a specialty of pharmacy practice. 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) The “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.

(B) The term “nuclear pharmacy” means the location where radioactive drugs, and chemicals within the classification of legend drugs, are compounded, dispensed, stored, or sold. 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 and/or the Missouri Department of Health.

(C) A “qualified nuclear pharmacist” 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 Pharmaceutical Specialties, a pharmacist who meets minimal standards of training for status as an authorized nuclear pharmacist or an authorized user of radioactive material, as specified by the Nuclear Regulatory Commission or by agencies of states that maintain certification agreements with the Nuclear Regulatory Commission.

(D) “Radiopharmaceutical services” means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

(E) “Quality control testing” means the performance of appropriate chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(F) “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.

(G) “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.
(H) “Radiopharmaceutical” means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons 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.

(2) General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(A) No person may receive, acquire, possess, compound or dispense any radiopharmaceutical except in accordance with the provisions of this rule and the conditions of rules and regulations promulgated by the Nuclear Regulatory Commission and/or the Missouri Department of Health. The requirements of this rule are in addition to and not in substitution of, other applicable statutes and regulations administered by the State Board of Pharmacy or the Missouri Department of Health.

(B) Nothing in this rule shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when the use of radiopharmaceuticals is limited to the diagnosis and treatment of patients under the supervision of the physician.

(C) Nothing in this rule shall be construed as requiring a licensed clinical laboratory, which is also licensed by the Nuclear Regulatory Commission and/or the Missouri Department of Health 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.

(D) Nothing in this rule shall be construed to require a department of nuclear medicine which is located in a hospital, which has a physician board certified in his/her specialty and which is licensed by the Nuclear Regulatory Commission and/or the Missouri Department of Health to handle radioactive materials, to obtain the services of a pharmacist or to have a nuclear pharmacy license for radiopharmaceutical preparation and distribution to patients within that institution.

(3) Permits.

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

(B) The permit to operate a nuclear pharmacy is effective only so long as the pharmacy also holds a current Nuclear Regulatory Commission and/or Missouri Department of Health license. Copies of inspection reports shall be made available upon request to the board for inspection.

(C) Any nuclear pharmacy which provides (transfers) product outside of a patient specific prescription service must be licensed as a drug distributor in order to provide a product for a prescriber’s use.
(4) Space, Security, Record Keeping and Equipment.

(A) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and as required by the Nuclear Regulatory Commission. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

1. Radiopharmaceutical preparation/dispensing area;
2. Radioactive material shipping/receiving area;
3. Radioactive material storage area; and
4. Radioactive waste decay area.

(B) The nuclear pharmacy professional service area shall be secured against unauthorized personnel and must be totally enclosed and lockable.

(C) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with State Board of Pharmacy, Nuclear Regulatory Commission and/or Missouri Department of Health statutes and regulations.

(D) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance. The State Board of Pharmacy recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards of purity and quality.

(E) A nuclear pharmacy shall have available the following resources:

1. A vertical laminar airflow hood that is annually certified to assure aseptic conditions within the working areas;
2. A sanitary work area that is designed to avoid outside traffic and outside airflow and that is ventilated so that it does not interfere with sanitary conditions. The sanitary work area shall not be used for bulk storage of supplies or other materials;
3. A sink located nearby that is suitable for cleaning purposes;
4. A current policy and procedure manual that includes the following subjects:
   A. Sanitation;
   B. Storage;
   C. Dispensing;
   D. Labeling;
   E. Record keeping;
   F. Recall procedures;
   G. Responsibilities and duties of supportive personnel;
   H. Training and education in aseptic technique; and
   I. Compounding procedures.

(5) Dispensing, Packaging, Labeling.
(A) A radiopharmaceutical shall be dispensed only to a licensed physician authorized by the Nuclear Regulatory Commission and/or the Missouri Department of Health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed physician. Except that a radiopharmaceutical may be transferred to a person who is authorized to possess and use the drug for nonclinical applications.

(B) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a licensed physician or the physician’s designated agent. Upon receiving an oral prescription order for a radiopharmaceutical, the nuclear pharmacy shall immediately have the prescription order reduced to writing or recorded in a data processing system. The order must be taken by a pharmacist, intern pharmacist, nuclear medicine technologist or designated agents. Nuclear medicine technologists may only receive prescription orders for diagnostic radiopharmaceuticals, and all such prescriptions must be reviewed and initialed by the pharmacist. The prescription record shall contain all information as required in 4 CSR 220-2.018 Prescription Requirements and shall also include:

1. The date of dispensing and the calibration time of the radiopharmaceutical; and
2. The name of the procedure.

(C) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with—

1. The name and address of the pharmacy;
2. The name of the prescriber;
3. The date of dispensing;
4. The serial number assigned to the order for the radiopharmaceutical;
5. The standard radiation symbol;
6. The words “Caution Radioactive Material”;
7. The name of the procedure;
8. The radionuclide and chemical form;
9. The amount of radioactivity and the calibration date and time;
10. If a liquid, the volume;
11. If a solid, the number of items or weight;
12. If a gas, the number of ampules or vials;
13. Molybdenum-99 content to United States Pharmacopoeia (USP) limits; and
14. The patient name or the words “Physician’s Use Only” in the absence of a patient name. When the prescription is for a therapeutic or blood-product pharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable from the physician upon demand.

(D) 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 radionuclide; and
4. The serial number of the radiopharmaceutical.

(E) When a radiopharmaceutical is dispensed under the authority of an Investigational New
Drug Application (IND), the nuclear pharmacy records shall include an investigator’s protocol
for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval
form (or letter) and a letter from the manufacturer (sponsor) indicating that the physician
requesting the radiopharmaceutical is a qualified investigator.

(6) Reference Manuals.
(A) Each nuclear pharmacy shall have a copy of the Missouri Pharmacy Practice Act and
current regulations under the act; one recognized text in nuclear pharmacy, and a current copy of
state and federal regulations governing the safe storage, handling, use, dispensing, transport and
disposal of radioactive material.

(7) Any preparation of Positron Emission Tomographic (PET) radiopharmaceuticals shall
comply with 4 CSR 220-2.200 Sterile Pharmaceuticals and with applicable USP standards.

AUTHORITY: sections 338.210, 338.240, 338.250, 338.280, 338.330(3), RSMo 1994 and
338.220 and 338.350, RSMo Supp. 1997.* This rule originally filed as 4 CSR 220-
Good afternoon, I am Michael Baxter, Director, Regulatory Affairs for the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

I would like to thank the FDA for holding a listening session to gather stakeholder input on preparation of radiopharmaceuticals as part of FDA’s efforts to ensure drug quality and security in the provision of safe, effective medications. As we have stated in our responses to previous Drug Quality and Security Act (DQSA) regulatory activity, most of the work of nuclear pharmacies or of pharmacists handling radiopharmaceuticals is not compounding. While compounding creates what are essentially new drug products designed to meet patient needs, most nuclear pharmacies are preparing radiopharmaceuticals from kits that are FDA-approved—activity that falls outside of the Food Drug and Cosmetic Act’s (FD&C) definition of compounding. Special difficulties arise with radiopharmaceutical preparations because of the radiation hazards and the potential for biological contamination when using instruments to minimize the radiation hazard. Therefore, because of the uniqueness of the practice of nuclear pharmacy/ working with radiopharmaceuticals, FDA policies are needed to account for differences—a position validated by USP’s decision to develop a new chapter, USP <825>, which will be specific for the preparation of radiopharmaceuticals.

APhA appreciates FDA’s release of the December 2016 draft Guidance for Industry Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies (hereinafter, the “Guidance”) to help clarify the applicability of DQSA and related FDA regulatory activity on the practice of nuclear pharmacy.1 Better clarifying radiopharmaceutical regulatory requirements and guidance at the federal level will help states correctly craft their policies to allow for the practice of nuclear pharmacy and/ or preparation of radiopharmaceuticals. APhA’s members appreciate the flexibility under this Guidance because it allows pharmacists to make needed adjustments to radioactivity, volume, and/ or the step-by-step procedures when preparing a patient-ready dose from an FDA-approved radiopharmaceutical product and dispense these unit doses based on patient time versus the name of the patient. APhA members are pleased FDA describes conditions under which it does not intend to take actions for violations of the FD&C, in particular section 505 (concerning new drug

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1 See 21 U.S.C. §353a(e). “(e) Application.--This section shall not apply to— `(1) compounded positron emission tomography drugs as defined in section 201(ii); or `(2) radiopharmaceuticals.” Available at: [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376733.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376733.htm)
approval requirements), section 502(f)(1) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements). However, there are provisions in the Guidance in which APhA requests clarification:

- **Applicability of the Guidance to Nuclear Regulatory Commission (NRC) licenses.** The Guidance very clearly states that it is not applicable to compounding or repackaging of radiopharmaceuticals that are not State-licensed nuclear pharmacies or federal facilities. However, due to that particular wording, there are other valid licenses incorrectly excluded from the Guidance’s purview. Licensing for hospital-based nuclear pharmacies and nuclear medicine departments are issued by the NRC, or an Agreement State, and therefore, depending on the state, would not necessarily be a State-licensed nuclear pharmacy. APhA believes it is not FDA’s intention to exclude this type of licensure from the Guidance. In addition, the Guidance provides that an authorized nuclear pharmacist, as defined by the NRC, must be identified on a RAM license. Broad scope radioactive material (RAM) licenses, which are typically issued to large academic institutions, do not specifically name personnel on the license. APhA asks FDA to clarify that the institutional radiation safety committee of a broad scope RAM license can name the authorized nuclear pharmacists, rather than restricting this requirement to the license itself.

- **Applicability to PET radionuclide kits.** Currently, the production of PET drugs are not addressed by the Guidance. Since the FDA approval of Gallium68 dotatate, the position of the FDA has been to treat this product as if it will be prepared in the nuclear medicine department or nuclear pharmacies. PET isotopes used as an approved ingredient as part of an FDA—approved radionuclide kit should be treated similarly in regulations and guidances as radiopharmaceuticals.

- **Terminology in reference to radiopharmaceuticals.** To better delineate acceptable practices, APhA members are requesting additional examples of situations that would be considered “minor deviations,” outside of FDA-approved labeling notated in the Guidance to better encompass the wide variety of products and practices. For example:
  - **Diluting** F-18 fludeoxyglucose (FDG), Tl-201 thallous chloride, or AdreView (Iobenguane I 123 Injection with normal saline (NS)) for the purposes of dispensing unit doses. This includes diluting multi-dose and single-dose vials taking into account factors such as buffers, bacteriostatic agents, and stabilizers that may already be present in the manufactured vial.
  - **Substituting a generator brand** from the brand mandated in the package insert as long as the two brands are essentially equivalent.
  - **Substituting a validated quality control test** such as media, solvents, and detectors for radiochemical or radionuclide purity testing.
  - **Substituting a heating plate** for a water bath where indicated in the package insert.

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4 See Lines 100-105. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM534811.pdf
• **Beyond Use Date (BUD) for radiopharmaceuticals.** As stated in our previous comments, APhA requests that FDA further clarify the effect of “(except for the BUD).”6 By excepting the BUD requirements of USP Chapters <795> and <797>, one would infer that there is no BUD requirement under the Guidance and therefore, pharmacists would rely on other state or federal requirements, if any, with regard to BUD. A BUD for radiopharmaceutical preparations should comply with USP standards for radiochemical purity, radionuclidic purity, chemical purity, sterility and stability, per the applicable USP monographs.

• **Reference to USP <795>.** According to the Guidance, an allowable “minor deviation” includes when a radiopharmaceutical is non-sterile and “compounded or repackaged in accordance with USP Chapter <795> (except for the BUD).”7 At present, USP Chapter <795> specifically exempts radiopharmaceuticals because of the “special training” involved that is “beyond the scope of this chapter.”8 Accordingly, FDA should remove this provision. As previously noted, USP is currently working on a stand-alone radiopharmaceutical (sterile and non-sterile) chapter.

APhA also urges FDA to reference, or otherwise include in its radiopharmaceuticals’ regulations and guidances, the current USP <797> language, which permits “the use of technologies, techniques, materials, and procedures” “so long as they have been proven to be equivalent or superior with statistical significance to those described herein.”9 Due to changing products, equipment, and evolving evidence, the use of techniques and procedures beyond those listed in the current USP Chapter <797>, is important to nuclear pharmacists and the practice of nuclear pharmacy and should not be prohibited if based on evidenced and do not negatively impact patients. These evidenced-based alternatives may actually be superior, such as those used to minimize the radiation exposure of personnel, and, in some cases, patients.

Finally, APhA continues to urge FDA to clarify certain provisions/language in FDA’s draft Guidance for Industry on Insanitary Conditions at Compounding Facilities that will be problematic to this important area of practice.10 This guidance discusses appropriate procedures in unidirectional air hoods.11 FDA should allow an accommodation for the temporary blocking of unidirectional air when necessary for the safe handling of radiopharmaceuticals in a vertical hood if patient safety is not affected to align with the practice of preparing radiopharmaceuticals. This guidance also contains language warning against “quick movement of personnel [that] disrupts the airflow and increases the risk of bringing lesser quality air into the ISO 5 area.” An exemption should be provided for the handling of radiopharmaceuticals as this language conflicts with existing requirements under 10 CFR 835 “Occupational Radiation Protection” to comply with ALARA (as low as reasonably achievable)12

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11 Ibid. See Lines 150-155. “Conducting aseptic manipulations or placing equipment/supplies in an area that blocks the movement of first pass air around an open container, whether before or after it is filled with sterile product. If unidirectional air over the critical surface is blocked, the area is no longer protected. If it is blocked by personnel conducting aseptic manipulations, contamination on personnel, particularly on exposed skin, could be introduced to the critical area.”

for shielding, distance and time requirements in regards to directional air in an ISO 5 environment for radiopharmaceuticals.

I would like to close by thanking FDA for continuing to work with APhA and other pharmacy stakeholders to provide regulatory clarity to pharmacists and pharmacies handling, preparing and repackaging radiopharmaceuticals. We would like to reiterate our willingness to be a resource for FDA, especially with regard to the practice of nuclear pharmacy. Thank you again for the opportunity to provide comments on this important issue.
15th May 2017

Kim Grinston, JD
Executive Director
Missouri Board of Pharmacy
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102

Dear Dr. Grinston,

Cardinal Health is the originator of centralized nuclear pharmacies and has always been the leader in setting standards for safe and effective radiopharmaceutical preparation. We presently operate 132 radiopharmacies in 45 states including three in the State of Missouri and dispense a substantial portion of the radiopharmaceuticals in the United States.

Just this past February 1st, Cardinal Health radiopharmacists participated in a radiopharmaceutical compounding roundtable held by the United States Pharmacopeial Convention (USP) at their offices in Washington DC. Our radiopharmacists brought great insight and clarity to the discussion and will continue to play a role in helping the USP to establish a separate chapter dealing with radiopharmaceutical compounding.

I am writing today to express our concerns with the interpretation of Missouri 20 CSR 2220 - 2.200 Sterile Compounding and its application to the practice of nuclear pharmacy. This correspondence will focus specifically on the creation and interpretation of the In-Use Time (IUT) concept.

The concept of an in-use-time is not present in the current United States Pharmacopoeia National Formulary (USP 40 NF 35) chapter <797> Pharmaceutical Compounding – Sterile Preparations. To my knowledge no State Board of Pharmacy other than Missouri has adopted the concept of an in-use-time into their regulations. The concept of in-use-times is present (lines 1505 – 1521) in the draft revisions to <797> that were released by USP for public comment in September of 2015. Pharmacist and practitioners were able to provide their comments to USP on this draft revision of <797> up until 31 January 2016.

On 27 January 2017 USP released a statement1 that “General Chapter <797> is currently undergoing revision. Initially, the proposed chapter revision was published for public comment from September 25, 2015 to January 31, 2016. During the public comment period, USP received more than 8,000 comments from more than 2,500 stakeholders. The Compounding Expert Committee is currently evaluating all of the information received in the public comments and using these data to inform the chapter revision as appropriate. Based on ongoing dialog and the nature and significance of the public comments received, the proposed revised chapter will be republished in the Pharmacopeial Forum for another round of public comments. Although General Chapter <797> is undergoing revision, the published version of the chapter which became official on June 1, 2008 is currently the official standard. At this time, USP does not have an anticipated date for the chapter’s republication.”

It seems ill advised to incorporate into regulations concepts that are not official, in draft form only and may never see the light of day in the final form of <797> once released. Surely the concept of “Show me” rings true with Missourians.

In the practice of nuclear pharmacy there are many examples of FDA-approved, commercially manufactured drug products prepared at the radiopharmacy which are a multi-dose container (MDC) that does not, nor could, contain a preservative. The MO BOP during discussions on definitions made a last minute change to reflect this fact by adding the phrase “…and usually contains an antimicrobial preservative.” This is congruent with USP<797>.

**USP <659> PACKAGING AND STORAGE REQUIREMENTS**

*Multiple-dose container* (also referred to as Multi-dose): A Container–closure system that holds a sterile medication for parenteral administration (injection or infusion) that has met antimicrobial effectiveness testing requirements, or is excluded from such testing requirements by FDA regulation. A Multiple-dose container is intended to contain more than one dose of a drug product. When space permits, a Multiple-dose container is labeled as such. Multiple-dose containers are generally expected to contain 30 mL or less of medications.

This is also supported by the very first chapter in the USP standards. It specifically lists when the MDC antimicrobial requirement is not required.

**USP <1> INJECTIONS AND IMPLANTED DRUG PRODUCTS (PARENTERALS)—PRODUCT QUALITY TESTS**

Antimicrobial agents must be added to preparations intended for injection that are packaged in multiple-dose containers unless one of the following conditions prevails: (1) there are different directions in the individual monograph; (2) the substance contains a radionuclide with a physical half-life of less than 24 h; or (3) the active ingredients are themselves antimicrobial.

The current MO BOP rules don’t specifically cover MDC’s without preservatives. There are restrictions on single-dose containers (SDC), pharmacy bulk containers and MDC with preservatives. It is inappropriate to attempt to lump any MDC’s without a preservatives into the classification of a single-dose container, as an interpretation of the absence of a preservative. One very common radiopharmaceutical prepared in the nuclear pharmacy is $^{99m}$Tc tetrofosmin (Myoview, GE Healthcare). This commercially manufactured drug product is a 30 mL vial containing the lyophilized drug that is prepared with the introduction of up to 2400 mCi of $^{99m}$Tc sodium pertechnetate. An adult dose is ~30 mCi of the radiopharmaceutical, allowing ~ 40 patient dosages to be withdrawn from this one vial. There is no antimicrobial compound present in this multidose vial and the package insert has the following language;

“Sodium Chloride Injection, USP must be used as the diluent if needed. The use of bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc99m injection may adversely affect the radiochemical purity and hence the biological distribution of the MYOVIEW Injection.”

The current MO BOP rules don’t specifically cover MDC’s without preservatives. There are restrictions on single-dose containers (SDC), pharmacy bulk containers and MDC with preservatives. For clarity, it is best to go back and look at the definitions in the published rules.

1. **Definitions**
   - Single-dose/single-unit container/vial: A container/vial of medication intended for administration that is meant for use in a single patient for a single case, procedure, or injection.
   - Multiple-dose container: A multiple unit container for articles or compounded sterile preparations that contains more than one (1) dose of medication and usually contains an antimicrobial preservative.
(9) Aseptic Technique and Preparation
(D) Single-dose vials/containers and pharmacy bulk vial/containers exposed to ISO Class 5 or cleaner air may be used in compounding until the assigned in-use time which shall not exceed six (6) hours after initial needle puncture, unless otherwise specified by the manufacturer. Opened single-dose ampules shall not be stored for any time period. The in-use time must be placed on the vial/container.
(E) Unless otherwise specified by the manufacturer, multiple-dose vials/containers with an antimicrobial preservative may be used in compounding until the assigned in-use date which shall not exceed twenty-eight (28) days after initially entering or opening the vial/container (e.g., needle-puncture). The in-use date must be placed on the vial/container.

It is inappropriate to consider an MDC without a preservative as a single dose product. The 30 mL vial of 99mTc Myoview with adult doses for ~ 40 patients is certainly not a single dose container. Nor is it appropriate to consider an MDC without a preservative as a pharmacy bulk container because they contain multiple patient doses. By definition, Pharmacy Bulk Packages (PBP) are restricted to only admixtures, allow a single piercing and have specific labeling requirements. Again, this does not accurately describe our products. For clarity, it is best to go back and look at the definitions in the relevant official published USP Chapter.

**USP <659> PACKAGING AND STORAGE REQUIREMENTS**
Pharmacy bulk package: A Container–closure system of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure must be penetrated only once after constitution, if necessary, with a suitable sterile transfer device or dispensing set that allows measured dispensing of the contents. The Pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean-air compounding area). Designation as a Pharmacy bulk package is limited to injection, for injection, or injectable emulsion dosage forms as defined in Nomenclature <1121>, General Nomenclature Forms.
Pharmacy bulk packages, although containing more than one single dose, are exempt from the Multiple-dose container volume limit of 30 mL and the requirement that they contain a substance or suitable mixture of substances to prevent the growth of microorganisms. See <7> for labeling requirements.

**USP <7> LABELING**
Pharmacy Bulk Package
Where a container is offered as a Pharmacy Bulk Package, the label shall: (a) state prominently "Pharmacy Bulk Package—Not for direct infusion"; (b) contain or refer to information on proper techniques to help assure safe use of the product; and (c) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under labeled storage conditions (see Packaging and Storage Requirements <659>).

We have been informed that the United States Pharmacopeial Convention (USP) has designated Chapter <825> as the future Radiopharmaceutical Compounding Chapter. We eagerly await this development and will be actively involved in its writing. It is suggested that the MO BOP consult with radiopharmaceutical compounding experts and convene an official nuclear pharmacy working group for additional guidance.

Nuclear pharmacy practice is searching for a reasonable scientifically based standard between the 6 hour proposed IUT and USP<797>’s 28 day BUD. It has been suggested that a rule limiting a maximum of 24 hours would be practical. This needs to be done because using the IUT in the manufacturer’s package insert has several issues and unintended consequences that do not provide greater patient protections.
The first reason is that none of the PI's, even the most recently approved – Lymphoseek in 2013 and updated in 2014, don't use the terms BUD or IUT. PI's use various phrases – some hard "use by X hours", "do not use after X hours"; some soft - "should not use after X hours". This is likely because most radiopharmaceutical (RP) clinical trials are conducted within teaching hospitals which either have the preparation within their own in-house nuclear medicine department for use during a certain shift. As such, there would not be an opportunity to collect extended use data that is needed by commercial nuclear pharmacies. Similarly, nuclear medicine physicians are not constricted by the PI in any way, so there would be no incentive for them to challenge for an extension.

The second being that many more PI's were written/approved decades ago. As such, it would be unlikely that the manufacturers expected the stated times to be implemented as hard restrictions on BUD, not to mention the recently created concept of IUT. An Authorized Nuclear Pharmacist (ANP) utilizes numerous resources to assist him/her in the process of developing procedures for the compounding of radiopharmaceuticals. One of these resources is the labeling provided with the drug product, commonly referred to as the manufacturer's package insert. A package insert accompanies all leged drugs in the United States and reflects the parameters and results of the clinical research and investigations that were conducted by the drug manufacturer in the process of applying for approval from the Food and Drug Administration. As approved labeling of the drug, it serves to limit the manner and extent that a drug manufacturer can market or promote their product. It does not limit a physician or pharmacist in how they can prescribe or prepare the drug.

Within the practice of medicine it is very common to utilize or prepare a drug, once approved by the FDA, in ways other than those tested in clinical trials by the manufacturer. The justification for such uses may be found in the medical literature. The decision of a medical professional to vary from language found in the package insert is one that is not made lightly, nor is it made without solid data supporting the reasons for the decision.

As advanced practice professionals, with highly specialized training, it should be expected that physicians and pharmacists would collaborate on providing these products for use on their patients. As physicians aren't restricted to PI, why should the pharmacists that compound their preparations be? Is this PI standard applied to all practice settings? Do other practice settings perform Quality Control testing on their CSP's? The BOP compounding rules allow "FDA-approved manufactured sterile products that are prepared differently than published in such labeling." If preparation is not limited to PI, why should the "use time" be limited to PI?

It should be pointed out that radiopharmaceuticals are the only specialty practice in pharmacy to get their own section within the chapter, yet no nuclear pharmacists (Board Certified or other) are in the 20+ member expert committee. Please take note that not a single document from these organizations use the MO BOP term IUT, but instead the industry standard term BUD.

We would like to reiterate the value of nuclear medicine procedures in patient care. The majority of the nuclear pharmacy community prepares radiopharmaceutical doses from conventionally manufactured products and requires a fully trained and recognized nuclear pharmacist to prepare the radiopharmaceutical for rapid distribution. The practical beyond use date (BUD) for most radiopharmaceutical patient dosages is 24 hours or less due to the short half-life of the radionuclide which is decaying rapidly. The concept of an In Use Time (IUT) is currently not supported by USP-<797> and its imposition would lead to patients being unable to receive the diagnostic imaging procedures that their physicians believe are necessary to their care.

Best regards,

Richard L. Green, R.Ph., BCNP
Chair, BPS Specialty Council on Nuclear Pharmacy
Nuclear Pharmacist on NRC's Advisory Council on the Medical Uses of Isotopes
Director of Radiopharmacy Practice
Standards of Operation for a Class F: Renal Dialysis Pharmacy

PURPOSE: This rule incorporates the provisions of SB 141 and defines minimum standards for a Class F: Renal Dialysis Pharmacy.

(1) A Class F pharmacy (renal dialysis) shall be limited in scope to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person’s home or specified address. Pharmacy services and dialysis supplies and products provided by a Class F pharmacy shall be limited to the distribution and delivery of drugs and devices as provided within this rule. All drugs and devices must be ordered by an authorized prescriber for administration or delivery to a person with chronic kidney failure for self-administration at the person’s home or specified address. All dialysis supplies and products provided by a Class F pharmacy shall be prepackaged and shall be covered by an approved New Drug Application (NDA) or 510(k) application issued by the Food and Drug Administration (FDA).

(2) A Class F pharmacy shall maintain a pharmacist-in-charge on a consultant basis who shall review pharmacy operations at least weekly. The pharmacist-in-charge of a Class F pharmacy will be responsible for the following requirements:

(A) Ensure that the use of legend drugs and devices that are provided to a person for the treatment of chronic kidney disease for self-administration at the person’s home or specified address shall be under the professional supervision of an appropriate practitioner licensed under Missouri law.

(B) Ensure that only drugs and devices that have been ordered by an authorized prescriber and are included on the list of approved formulary drugs and devices are provided to patients;

(C) Ensure that no drugs or devices shall be dispensed to a patient until adequate training in the proper use and administration of such products has been completed;

(D) Ensure that proper documentation of drug and device distributions and deliveries are maintained by the Class F pharmacy and are made available upon request to practitioners involved in the care of the patient and to board of pharmacy representatives;

(E) Maintain a policy and procedure manual that shall be available for inspection by board of pharmacy personnel. The manual shall include a quality assurance program with which to monitor the qualifications, training and performance of personnel; and

(F) The pharmacist-in-charge shall be responsible for the drug/device delivery system and shall establish a written protocol for the implementation of the delivery system including methods for supervising drug/device deliveries to patients of the pharmacy.

1. Any written protocols shall be available for inspection by board of pharmacy personnel.

2. Any changes to the policy and procedure manual or to written protocols must be approved by the pharmacist-in-charge.
(3) Drug Formulary List/Device List. The pharmacy shall submit a list of drugs and/or devices which must be approved by the board of pharmacy.

(4) A Class F pharmacy shall deliver products to a person with chronic kidney failure only upon the receipt of a valid prescription from an authorized prescriber specifying or including:

(A) Documents that the intended recipient will require such products for the appropriate treatment of the disease and that the intended recipient has been trained in home dialysis therapy;

(B) The duration of the prescriber’s order, not to exceed one (1) year, including all authorized refills; and

(C) The name and product code of each product prescribed and the quantity prescribed.

(5) Personnel of the pharmacy shall assemble the products to be delivered pursuant to the prescriber’s order(s). In assembling such products for delivery, the pharmacy shall take steps necessary to assure the following:

(A) The code numbers and quantities of the products assembled match the code numbers identified in the prescriber’s order(s);

(B) Any products bearing an expiration date have a minimum of three (3) full months of shelf-life remaining;

(C) A visual inspection of all drugs and devices for compliance with the prescriber’s order(s) and with all labeling requirements as set forth in 338.059, RSMo. Manufacturer sealed case lots shall be labeled with the name of the patient, date, and a control number that serves as a unique patient identifier number; and

(D) Products ordered by a prescriber and provided to patients of the pharmacy shall be delivered either by personnel of the pharmacy or by a carrier authorized by the pharmacy.

1. Upon the delivery to patients of any drugs/devices, pharmacy personnel or the approved carrier shall confirm receipt by the patient or the patient’s designee and that the number of units delivered equals the number of units identified by documentation supplied by the pharmacy.

(6) Class F pharmacies shall comply with all of the following:

(A) The license of the pharmacy shall be displayed in plain view at the pharmacy location;

(B) The pharmacy shall be open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescriber;

(C) The pharmacy must maintain sufficient space and storage capabilities as necessary to carry out its operations; and

(D) All drugs and/or devices shall be properly identified and any outdated, misbranded or adulterated items shall be segregated from the active inventory within a clearly separate and defined area and shall be held separately until the item is destroyed or returned to a licensed drug distributor.

Standards of Operation/Licensure for Class L Veterinary Pharmacies

PURPOSE: This rule defines standards for a Class L veterinary pharmacy.

(1) A Class A or a Class L pharmacy permit shall be required for any entity engaged in the sale, dispensing, or filling of a legend drug for use in animals that must only be dispensed by prescription under state or federal law. For purposes of this rule, a legend drug shall be defined as provided by 21 USC section 353.

(2) Class A Pharmacies. Class A permit holders shall comply with all laws/rules applicable to Class A pharmacies, provided a Class A pharmacy shall comply with sections (7) and (8) of this rule when legend drugs are dispensed for animal use.

(3) Class L Pharmacies. A Class L pharmacy shall dispense, sell, or provide legend drugs only for animal use. Except as otherwise provided in this rule, a Class L pharmacy shall comply with all applicable state and federal pharmacy and controlled substance laws/rules including, but not limited to, all applicable provisions of Chapter 338, RSMo, and the rules of the board.

(4) Pharmacy Operations. A Class L pharmacy shall comply with 20 CSR 2220-2.010, with the following allowed modifications:

(A) The pharmacy permit shall be displayed in plain view at the pharmacy location;

(B) The pharmacy shall maintain sufficient space, equipment, and storage capabilities as necessary to carry out its operations;

(C) Legend drugs shall be properly identified and stored in a defined area within the pharmacy;

(D) Legend drugs shall be stored in a clean and sanitary designated area and within temperature requirements as provided for by the manufacturer or the latest edition of the United States Pharmacopoeia (USP);

(E) The pharmacy shall maintain a current reference manual related to veterinary drugs that complies with 20 CSR 2220-2.010(1)(D);

(F) Appropriate sewage disposal must be available within the pharmacy and a hot and cold water supply shall be accessible to pharmacy staff. If compounding is performed, the hot and cold water supply shall be located within the pharmacy;

(G) Pharmacy compounding shall comply with 20 CSR 2220-2.200, 20 CSR 2220-2.400, and all other applicable provisions of state/federal law;

(H) All dispensing errors shall be documented in the pharmacy’s records;

(I) Animals shall not be allowed in the designated area where legend drugs are stored or maintained; and

(J) The pharmacist-in-charge shall be notified within twenty-four (24) hours after a dispensing error is learned by pharmacy staff. Documentation of notification shall be maintained in the pharmacy’s prescription records.
A Class L pharmacy shall designate a pharmacist-in-charge as required by 20 CSR 2220-2.010(1)(M). The pharmacist-in-charge shall be responsible for supervising pharmacy operations and ensuring compliance with the provisions of this rule and all applicable state/federal laws.

Except as otherwise provided in this rule, the pharmacist-in-charge shall also—

(A) Ensure legend drugs are only sold, dispensed, or filled by the pharmacy for animal use;

(B) Ensure legend drugs have been ordered/prescribed by an authorized prescriber; and

(C) Maintain a policy and procedure manual for pharmacy operations. The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge. The manual shall be available for inspection by board personnel and shall include policies and procedures for:

1. Accepting, compounding, dispensing, or filling prescriptions;

2. Accepting, dispensing, or filling prescriptions in the pharmacist’s absence;

3. Drug storage and security;

4. Handling drug recalls;

5. Procedures for offering patient/client counseling;

6. If applicable, procedures for dispensing or providing prescriptions in a pharmacist’s absence pursuant to section (8) of this rule;

7. Contacting the pharmacist-in-charge for consultation during the pharmacy’s business operations or in the event of an emergency; and

8. Reporting and handling dispensing errors. The pharmacist-in-charge shall be notified of a dispensing error within twenty-four (24) hours after the error is learned by pharmacy staff. Policies/procedures shall include the manner of notification.

A pharmacist shall not be required to be physically present on-site during the business operations of a Class L pharmacy if the pharmacist-in-charge reviews the activities and records of the pharmacy operations on a monthly basis to ensure compliance with this rule. This exemption shall not apply if the pharmacy sells, dispenses, or otherwise provides controlled substances. The date of the pharmacist-in-charge review shall be documented and maintained at the pharmacy.

To be valid for purposes of dispensing, legend drug prescriptions for animal use shall conform to all requirements of sections 338.056 and 338.196, RSMo, and shall contain the following:

(A) The date issued;

(B) The client’s/owner’s name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;

(C) The prescriber’s name, if an oral prescription, or signature, if a written prescription;

(D) Name, strength, and dosage form of drug and directions for use;

(E) The number of refills, when applicable;

(F) The quantity prescribed in weight, volume, or number of units;

(G) The address of the prescriber and the patient when the prescription is for a controlled substance;
(H) Whether generic substitution has been authorized;

(I) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(J) Controlled substance prescriptions shall comply with all requirements of federal and state controlled substance laws.

(8) Dispensing. A Class L pharmacy may accept, fill, enter, dispense, or otherwise provide non-controlled legend drugs for animal use in the absence of a pharmacist, provided the pharmacist-in-charge shall review the prescription record for each such prescription on a monthly basis. The review shall be documented as provided in section (6) of this rule. For purposes of 20 CSR 2220-2.010(3), the dispensing pharmacist shall be identified as the pharmacist-in-charge unless dispensed by another licensed pharmacist.

(A) Legend drugs may only be compounded for use in animals when a pharmacist is present on site.

(B) Clients must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site, a written offer to counsel with a contact telephone number for a pharmacist shall be supplied with the medication.

(9) Labeling. Prescriptions must be labeled as required by section 338.059, RSMo. Prescription labels may be manually written and numbered and shall include:

(A) The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and

(B) If applicable, the veterinarian’s specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal(s).

(10) Records. Class L pharmacy records shall be maintained as required by Chapter 338, RSMo, and the rules of the board, including, 20 CSR 2220-2.018 and 20 CSR 2220-2.080.

(A) The information specified in section (7) of this rule shall be required and recorded on all handwritten, telephone, oral, and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy. If applicable, prescription records shall also include the veterinarian’s specified withdrawal, withholding, or discard time identified in section (9) of this rule.

(B) Any change or alteration made to the prescription dispensed based on contact with the prescriber shall be documented in the pharmacy’s prescription records. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(C) The pharmacy’s prescription records shall identify any prescription dispensed in a pharmacist’s absence pursuant to section (8) of this rule.

(11) A Class L pharmacy shall comply with all applicable state or federal controlled substance laws.
(12) The provisions of this rule shall not be applicable to the sale of medication for use in animals that may lawfully be dispensed without a prescription nor shall this rule be construed to require licensure for entities solely engaged in selling, dispensing, or providing medications authorized for dispensing without a prescription.

(13) The provisions of this rule shall not prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or dispensing of their own prescriptions, medicine, drug, or pharmaceutical product to be used for animals.


PURPOSE: This rule implements the provisions of section 338.400, RSMo, and establishes pharmacy standards for dispensing blood-clotting products.

(1) Definitions. The following definitions are hereby adopted and applicable to this rule:

(A) “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, acquired hemophilia, von Willebrand’s disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood-clotting. As defined by section 338.400, RSMo, “bleeding disorder” does not include a bleeding condition secondary to another medical condition or diagnosis, except for acquired hemophilia;

(B) “Blood-clotting product,” a medicine approved for distribution by the federal Food and Drug Administration (FDA) that is used for the treatment and prevention of symptoms associated with bleeding disorders, including, but not limited to, recombinant and plasma derived factor products, von Willebrand factor products, antifibrinolytics, bypass products for patients with inhibitors, prothrombin complex concentrates, and activated prothrombin complex concentrates. Except as otherwise provided by section 338.400, RSMo, a “blood-clotting product” does not include medical products approved solely for the treatment or prevention of side effects of a blood-clotting drug or medication;

(C) “Established patient,” For purposes of section 338.400, RSMo, and this rule, an “established patient” shall be defined as a bleeding disorder patient that has been dispensed a legend blood-clotting product by the pharmacy on more than three (3) occasions in a single calendar year; and

(D) “Pharmacy,” an entity engaged in the practice of pharmacy as defined in section 338.100, RSMo, that provides blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders.

(2) General Requirements. All Missouri licensed pharmacists and pharmacy permit holders shall comply with the following requirements when dispensing blood-clotting factor concentrates:

(A) Prescriptions for blood-clotting factor concentrates shall be dispensed as written or authorized by the prescribing physician, in accordance with state and federal law. No changes or substitutions shall be made unless approved by the prescriber. If the pharmacy has received prescriber authorization to change or substitute the blood-clotting factor concentrate originally prescribed, the patient or the patient’s designee shall be notified and counseled regarding the change or substitution prior to dispensing via the preferred contact method identified by the patient or designee pursuant to subsection (2)(E);
(B) If requested by the patient or the patient’s designee, the pharmacy shall ship and deliver blood-clotting factor concentrates to the patient or the patient’s designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations. Nonemergency situations shall include, but may not be limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices must be used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements;

(C) Patients must be provided with a designated pharmacy contact telephone number for reporting problems with a delivery or product on each dispensing at no cost to the patient;

(D) Unless otherwise authorized by the patient or the patient’s designee, the pharmacy shall contact the patient for authorization to dispense prior to shipping a refill of any blood-clotting product to the patient. The date of patient authorization shall be documented in the pharmacy’s prescription records;

(E) Barring extenuating circumstances, prescriptions for blood clotting factor concentrates shall be dispensed within plus or minus ten percent (10%) of prescribed assays, or as otherwise authorized or directed by the prescriber; and

(F) Recalls or Withdrawals. Prior to dispensing any blood clotting factor concentrate, the pharmacy shall ask the patient or the patient’s designee to designate a preferred contact method for receiving notifications in the event of a recall or withdrawal of the concentrate dispensed or any related ancillary infusion equipment and supplies dispensed by the pharmacy. The preferred contact method shall be documented with the patient information required by 20 CSR 2220-2.190(2).

1. Notice of concentrate or ancillary infusion equipment and supplies recalls and withdrawals shall be provided to the patient via the patient’s preferred contact method within twenty-four (24) hours of receipt of a recall or withdrawal notification from the manufacturer or any state or federal entity that requires or recommends patient notification. The pharmacy shall also notify the prescribing physician within twenty-four (24) hours of such recall or withdrawal and shall obtain a prescription for an alternative product if a new or amended prescription is required to dispense or deemed necessary and appropriate by the prescriber.

2. If attempts to contact the patient via the preferred contact method are unsuccessful, the pharmacy shall mail notification to the patient or the patient’s authorized designee within the required twenty-four (24) hours or the next business day.

3. The time, date, and method of notification to the patient and prescriber shall be documented in the pharmacy’s records and maintained for two (2) years from the date of recall or withdrawal.

(3) In addition to the provisions of section (2), pharmacies that dispense blood-clotting products to established patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, shall comply with the following standards of care:
(A) The pharmacy shall annually notify the board in writing of the pharmacy’s intent to provide legend blood-clotting products for bleeding disorder patients. Notification shall be made on or before January 31 of each calendar year in a manner and form approved by the board;

(B) The pharmacy shall identify in advance, or make arrangements with, a supplier or suppliers capable of providing all brands, assays, and vial sizes of blood-clotting products approved by the federal FDA, including products manufactured from human plasma and those manufactured from recombinant technology techniques. A list of all designated or identified suppliers shall be maintained at the pharmacy and made available during inspection. This requirement shall not be construed to require a pharmacy to purchase products prior to receiving a valid prescription order;

(C) A pharmacist shall be available twenty-four (24) hours a day, seven (7) days a week, every day of the year, either on-site or on call, to fill prescriptions for blood-clotting products, within the time frames designated by section 338.400, RSMo, and the provisions of this rule;

(D) Pharmacists engaged in dispensing or filling blood-clotting factor concentrates or who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients shall have sufficient knowledge, experience, and training to perform the duties assigned. To ensure continued competency, pharmacists engaged in counseling bleeding disorder patients shall complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment or therapy, or blood-clotting disorders or diseases each biennial renewal period. The continuing education required by this rule may be used to satisfy the pharmacist’s continuing education requirements. Proof of compliance with this section shall be maintained at the pharmacy for a minimum of four (4) calendar years and shall be made available during inspection or at the request of the board;

(E) If requested by the patient or the patient’s designee, the pharmacy shall provide for the shipment and delivery of blood-clotting products to the patient or the patient’s designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations;

(F) Established patients shall be provided access to blood-clotting products within twelve (12) hours of notification from a physician of the patient’s emergent need for a blood-clotting product. For purposes of this section, determination of an emergent need shall be within the professional medical judgment of the physician. Emergent need requests shall be documented in the pharmacy’s prescription records;

(G) The pharmacy shall provide or have available for purchase containers for the disposal of hazardous waste, including, but not limited to, sharp or equivalent biohazard waste containers;

(H) At a minimum, the pharmacy shall provide or have available for purchase ancillary 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, and cold compression packs. If supplies are depleted, the pharmacy shall restock the required ancillary equipment and supplies in a reasonable amount of time which shall not exceed seven (7) calendar days;
(I) The pharmacy shall have contact information available for a nurse or nursing service or agency with experience in providing infusion related nursing services or nursing services for bleeding disorder patients if such services are not provided by the pharmacy;

(J) If requested by the patient or the patient’s authorized designee, the pharmacist shall explain any known insurance copayments, deductibles, coinsurance payments, or lifetime maximum insurance payment limits. For purposes of complying with this section, the pharmacy may rely on information supplied by the patient’s insurer; and

(K) The pharmacy shall register with the National Patient Notification System, or its successor, to receive recall notification for all products included in the National Patient Notification System. The pharmacy shall maintain current and accurate contact information with the National Patient Notification System.

(4) Pharmacies that provide legend blood-clotting products to treat or prevent symptoms of established bleeding disorder patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, shall develop and follow written policies and procedures to ensure compliance with section 338.400, RSMo, and the provisions of this rule. The pharmacy shall review the policies and procedures on an annual basis and document such review. At a minimum, the pharmacy’s written policies and procedures must include procedures for:

(A) Processing prescriptions for blood-clotting products by pharmacy staff to ensure the timely handling and dispensing of blood-clotting products;

(B) Processing partial fill requests by patients to reduce or eliminate excessive dispensing;

(C) Providing and documenting recall notifications in accordance with this rule;

(D) Transferring, dispensing, refilling, or delivering blood-clotting factor concentrates to established patients in the event of an emergency or disaster;

(E) Notifying patients prior to terminating business or terminating the dispensing of any blood-clotting factor concentrate or prior to a known or an anticipated termination of pharmacy services for a bleeding disorder patient. Notification shall be provided in writing and, when reasonably possible, shall be provided a minimum of seven (7) days prior to any such termination;

(F) Shipping or providing blood-clotting products to the patient within the time frames required herein;

(G) Receiving, processing, and dispensing prescription or dispensing requests for a blood-clotting product to bleeding disorder patients, including procedures for handling and processing physician request indicating a patient’s emergent need for a blood-clotting product;

(H) Ensuring appropriate cold chain management and packaging practices are used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements; and

(I) Handling and processing preauthorization notifications and requests and communicating preauthorization requirements to the patient and applicable prescriber.
(5) This rule shall not be construed to require dispensing without appropriate payment or payment arrangements. If the pharmacy is waiting for authorization, certification, or other action from a third-party payer prior to dispensing, the pharmacy shall notify the patient that the prescription is available for dispensing and explain any alternative payment options. Notification shall be provided as soon as reasonably practicable. At a minimum, however, notification shall be provided to the patient prior to the expiration of the shipping and delivery time frames required by subsection (2)(E), (3)(B), or (3)(F) of this rule.


#A7. **Draft Rules Under Review**

- 20 CSR 2220-2.010 Pharmacy Standards of Operation (Draft)
- 20 CSR 2220-2.012 Pharmacy Supervision
- 20 CSR 2220-2.025 Non-Resident Pharmacies
- 20 CSR 2220-2.090 Pharmacist-In-Charge
- 20 CSR 2220-2.950 Automated Filling Systems
- 20 CSR 2220-6.040 Administration by Medical Prescription Order (Draft)
- 20 CSR 2220-6.050 Administration of Vaccines Per Protocol (Draft)
20 CSR 2220-2.010 Pharmacy Standards of Operation

PURPOSE: This rule defines terms used in the regulations of the State Board of Pharmacy and outlines the conditions necessary for the operation of a pharmacy.

(1) All pharmacies licensed by the Board shall comply with all applicable state and federal law governing pharmacy practice and medication handling, including, but not limited to, all applicable patient counseling, compounding, controlled substances and medication dispensing, disposal and distribution laws and regulations.

(2) Pharmacist-In-Charge. Except as otherwise authorized by law, pharmacies must be under the supervision of a pharmacist-in-charge that has been designated with the Board who is responsible for managing the pharmacy and supervising pharmacy staff.

(A) The pharmacist-in-charge must hold a current and active Missouri pharmacist license or, for pharmacies located outside of Missouri, a current and active pharmacist license in the state where the pharmacy is located.

(B) If the designated pharmacist-in-charge changes, the pharmacy may not continue operations until a new pharmacist-in-charge is named. A change of pharmacist-in-charge application must be submitted to the Board with the applicable fee within fifteen (15) calendar days after a new pharmacist-in-charge is designated. A controlled substance inventory must be taken at or immediately prior to a pharmacist-in-charge change as required by 20 CSR 2220-2.090.

(3) Pharmacy Equipment and Reference Materials. Pharmacies must be equipped with proper pharmaceutical equipment and reference materials for the pharmacy services performed. Equipment must be maintained in good working order and capable of properly functioning.

(A) A current edition of statutes and rules governing the pharmacy’s practice must be manually maintained or electronically available at the pharmacy, including, but not limited to, Chapters 338 and 195, RSMo, 20 CSR 2220 and, if applicable, 19 CSR 30 governing controlled substances;
(B) Pharmacies must be equipped with basic equipment for the pharmacy services provided as recognized by the latest edition of the United States Pharmacopoeia (USP), the United States Pharmacopoeia/Drug Information (USP/DI) or Remington’s Pharmaceutical Sciences.

(C) A device or other equipment must be maintained for numbering or uniquely identifying prescriptions and medication orders along with appropriate equipment for producing prescription/medication order labels.

(D) Reference materials may include any generally recognized or peer-reviewed pharmaceutical publication. At a minimum, the pharmacy must maintain or have electronically available the current or latest edition of reference(s) or other resource(s) which includes all Federal Drug Administration (FDA)-approved drugs. Additionally, the pharmacy must maintain or have electronically available reference materials that include the following topics:

1. Pharmacology of drugs;
2. Dosages and clinical effects of drugs;
3. Patient information and counseling; and
4. Sterile or non-sterile compounding, if applicable.

(E) The required resources/references may be maintained electronically provided the resource/reference is immediately accessible when requested by the Board or a Board authorized designee.

(4) General Standards of Operation. Except as otherwise provided by law, all Board licensed pharmacies must comply with the following:

(A) All Missouri and federal pharmacy licenses, permits or registrations must be current and accurate, including, the pharmacy’s permit classification(s). Changes in the pharmacy’s name, address location or permit classification(s) must be timely and accurately submitted to the Board.

(B) Medication must be properly and accurately prepared, packaged, dispensed, distributed and labeled.

(C) The pharmacy must be maintained in a clean and sanitary condition. The preparation, dispensing or compounding of drugs or drug-related devices must be completed under clean and, when required, aseptic conditions.

1. Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law. Except as otherwise authorized by the Board, appropriate
sewage disposal and a hot and cold water supply must be available within the pharmacy. The
required water supply may not be located within a bathroom.

2. Appropriate sanitation, lighting, ventilation and humidity must be maintained in areas
where drugs are stored or dispensed. Shelves, aisles, walkways and medication storage or
handling areas must be kept clear of debris, dirt or filth. Trash must be disposed of in a timely
manner. Medication shall not be stored on the floor or near trash areas.

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

(D) Medication must be maintained within temperature requirements recommended by the
manufacturer or the United States Pharmacopeia (USP), or both. Drug storage areas must be
maintained thermostatically to ensure drug storage within proper temperature requirements.
Temperature recording equipment must be used to document proper temperature storage in drug
storage areas, including, in refrigerators and freezers. Temperature recordings must be reviewed
and documented each day the pharmacy is in operation. Alternatively, a continuous
temperature monitoring system may be used if the system maintains ongoing documentation of
temperature recordings that are reviewed daily. Proof of compliance with this subsection must
be maintained in the pharmacy’s records.

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

(F) Adequate security and locking mechanisms must be maintained to prevent unauthorized
pharmacy access and to ensure the safety and integrity of drugs and medication records,
including any drugs/records stored at an authorized offsite storage facility registered with the
Board. Traffic in the pharmacy must be restricted to authorized persons so that proper control
over drugs and confidential records can be maintained at all times.
If the pharmacy is located in a facility that is accessible to the public and the pharmacy’s hours of operation are different from those of the remainder of the facility, ceilings and walls must be constructed of plaster, drywall or other substantial substance so that the pharmacy permit area is separate and distinct from the remainder of the facility. Drop down ceilings that would allow unauthorized access into the pharmacy are not allowed;

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

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

2. Storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and will be subject to inspection by the board as defined in section 338.150, RSMo.

3. Storage of controlled substances or controlled substance records must comply with state and federal controlled substance laws.

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

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

All individuals practicing or assisting in the practice of pharmacy must be appropriately licensed or registered with the Board and must be appropriately trained for the duties performed.

Except as otherwise provided by law, the pharmacy must be supervised by a Missouri-licensed pharmacist at all times when prescriptions are being prepared, compounded, dispensed or sold and whenever technicians are assisting in the practice of pharmacy.

If the pharmacy is open to the public, all Board licensees and registrants must wear an identification badge or similar identifying article that identifies their name and applicable
license/registration when practicing or assisting in the practice of pharmacy (e.g., pharmacist, pharmacy technician, intern pharmacist). Licenses and registrations must also be conspicuously posted in the pharmacy with a photo attached that is not smaller than two by two inches (2” x 2”). Alternatively, licenses and registrations may be maintained in a central location within the pharmacy with the required photo, provided the licenses/registrations are immediately retrievable during an inspection.

(L) Licensees/registrants working for more than one (1) pharmacy must have in their possession official proof of licensure/registration issued by the Board (e.g., wallet card or official online verification from the Board website).

(M) Licensees/registrants shall notify the Board of a change of personal or employment address no later than thirty (30) days after the change. Notification must be electronically submitted in a form provided by the Board.

(N) A technician list must be maintained of all current pharmacy technicians that includes the technician’s name and registration number or a copy of a completed registration application that has been submitted to the board. The technician list must be immediately available at the request of the Board or the Board’s authorized designee. The pharmacist-in-charge and the permit holder are jointly responsible for determining which individuals must be registered as a technician.

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

(P) Pharmacies must notify the board in writing or electronically within fifteen (15) days of any final disciplinary action taken against a pharmacist, intern pharmacist or pharmacy technician licensed/registered by the Board. The notification must include:

1. The pharmacy’s name and permit number;
2. Name of person making the notification;
3. The licensee’s or registrant’s name and license/registration number;
4. Date of action;
5. Reason for action; and
6. Any additional information required by law.

(5) Every pharmacy shall designate as its primary means of record keeping either a manual system which provides for the sequential numbering or unique identification of hard copy prescriptions/medication orders and complies with the provisions of section (6) of this rule or an electronic system which complies with the provisions of 20 CSR 2220-2.080. The designated record system shall be used to record the pharmacy’s dispensing of all drugs, medicines and poisons.

(6) Each pharmacy shall maintain at least three (3) separate files of prescriptions and medication orders as follows:

(A) A separate file for Schedule I and II controlled substances;

(B) A separate file for Schedules III, IV and V controlled substances; and

(C) A separate file(s) for all other prescriptions/medication orders for non-controlled drugs.

(7) Pharmacies shall maintain inventories and records of the receipt, distribution or other disposition of legend drugs. At a minimum, distribution records must include:

(A) Date of the transaction/distribution;

(B) Product name, strength and quantity;

(C) The names of the parties; and

(D) The receiving entity’s address.

(8) No outdated, misbranded or adulterated drugs may be dispensed or maintained within the pharmacy’s active inventory, including prescription and related nonprescription items. Outdated, misbranded or adulterated medication or medication for personal employee use must be quarantined in an area that is clearly identified and physically separate from medication maintained for dispensing, distribution or other pharmacy use. Medication for the personal use of pharmacy staff or personnel must be labeled in accordance with section 338.059, RSMo, or as otherwise required by law.
(9) Pharmacy records must be accurately and properly maintained in compliance with applicable state and federal law, including all applicable controlled substance laws. Records required by Chapters 195 and 338, RSMo or divisions 20 CSR 2220 and 19 CSR 30 shall be available for inspection, photocopying, photographing or electronic duplication by a board of pharmacy representative. Unless otherwise provided by law, records required by Chapter 338 or 20 CSR 2220 that do not have a specified retention time must be kept for two (2) years and must be readily retrievable at the request of the Board or the Board’s authorized designee.

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

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

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

1. Injectable dosage forms of sodium chloride and water;
2. Irrigation dosage forms of sodium chloride and water;
3. Injectable dosage forms of heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;
4. Injectable dosage forms of diphenhydramine and epinephrine;
5. Vaccines indicated for public health needs, such as influenza, pneumonia, hepatitis A and hepatitis B; and
6. Tuberculin test material.

(B) The agency shall have a policy and procedure that addresses at least the following:

1. Specific drugs authorized to be possessed by the agency and the nurse;
2. Indications for use of the drugs possessed;
3. Receiving orders from an authorized prescriber for drug administration;
4. Leaving drugs with the patient for routine care procedures;
5. Conditions for storing and transporting drugs by the agency and nurse; and
6. Quantity of drugs possessed by the agency and nurse.
(C) The nurse must have authorization from an authorized prescriber, such as an individual patient order, protocol or standing order, to administer the drugs.

(D) Up to a two (2)-week supply of sodium chloride, water, and heparin may be left with the patient provided the patient or the patient’s representative has been instructed verbally or in writing on how to perform the procedure. Drugs left with the patient shall be labeled with instructions for use. A record shall be made of all drugs left with the patient in the patient’s medical record. Drugs left with the patient may not be returned to the agency.

(E) Drugs may be stored at the agency or transported by the nurse, and shall be stored or transported at all times in accordance with the manufacturer’s storage requirements. Refrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

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

(12) A Class-I pharmacy within a residence must be located in a separate room that has a door with a suitable lock. Patients shall not be allowed in a Class-I pharmacy located within a residence. Other than a Class-I pharmacy, no pharmacy permit shall be issued to any location, that is located in a residence regardless of zoning.

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

20 CSR 2220-2.012 Pharmacy Supervision

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

(1) Definitions.

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

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

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

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

(B) A sign must be prominently displayed on the pharmacy counter advising the public when no pharmacist is on duty. The sign must be displayed in an area where medication is dispensed to patients in a manner that is easily viewable by the public; sign lettering must be a minimum height of two inches (2”).

(C) A pharmacist must verify the accuracy of prescription or medication order data on each original prescription or medication order prior to dispensing. Additionally, a pharmacist must personally inspect and verify the accuracy of the final contents and affixed label of each prescription or medication order prior to dispensing.
(D) If authorized by a pharmacist, licensed/registered pharmacy technicians and intern pharmacists may perform the following activities when a pharmacist is absent:

1. Accept written prescriptions or medication orders from a patient, provided the prescription or medication order may not be prepared, compounded, dispensed, filled or entered into the pharmacy’s prescription/medication system without a pharmacist present and supervising;

2. Receive medication deliveries, however, the medication may not be stocked or otherwise handled without a pharmacist present; and

3. When a pharmacist is temporarily absent from the pharmacy permit area, final, complete and labeled prescriptions or medication orders that have been verified by a pharmacist may be dispensed to the patient if the pharmacist is physically present on the pharmacy’s premises and able to provide assistance in the event of an emergency. If pharmacist counseling is requested, the medication may not be dispensed until the pharmacist is present or, at the patient’s option, a contact number for the patient can be collected for the pharmacist to call on return. If the temporary absence exceeds thirty (30) minutes, the no pharmacist on duty sign must be posted and no further dispensing shall take place until a pharmacist is present and supervising. Medication may not be dispensed during an authorized temporary absence if a pharmacist prohibits dispensing or indicates counseling is mandatory.

(3) Intern Pharmacists. Pharmacist preceptors shall be responsible for all pharmacy activities performed by an intern pharmacist while under his or her supervision.
20 CSR 2220-2.025 Nonresident Pharmacies

PURPOSE: This rule establishes licensure guidelines for nonresident pharmacies.

(1) Nonresident pharmacies shall not ship, mail or deliver prescription drugs into Missouri without first obtaining a pharmacy license from the Missouri Board of Pharmacy. An exemption to licensure is allowed when a nonresident pharmacy provides a prescription drug in an emergency situation or supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located or provides medications upon receipt of a prescription or physician order for patients in institutional settings and the nonresident pharmacy is not recognized as a primary provider.

(2) To obtain a license as a Missouri pharmacy license, a nonresident pharmacy must comply with each of the following:

(A) Maintain a pharmacy license in good standing from the state in which the nonresident pharmacy is located;

(B) Submit an application as provided by the Missouri Board of Pharmacy for licensure in compliance with 4 CSR 2220-2.020(2) and (3) 20 CSR 2220-2.020(2), (3), (9) and (10);

(C) Pay all appropriate licensing fees;

(D) Submit a copy of the state pharmacy license from the state in which the nonresident pharmacy is located; and

(E) Submit a copy of the state and federal controlled substance registrations from the state in which it is located, if controlled substances are to be shipped into Missouri. If controlled substances will be shipped into Missouri, submit a copy of the applicant’s federal controlled substance registration and, if applicable, a copy of the applicant’s state controlled substance registration from the state where the applicant is located;

(F) If the designated pharmacist-in-charge does not have a current and active Missouri pharmacist license issued by the Board, submit an official verification from the state board of pharmacy or equivalent state pharmacist licensing agency verifying that the designated pharmacist-in-charge holds a current and active pharmacist license in the state in which the nonresident pharmacy is located; and
(G) Submit a copy of the applicant’s most recent pharmacy inspection by the applicant’s resident state board of pharmacy or its equivalent state regulatory body. The inspection must have occurred within the last eighteen (18) months for sterile compounding pharmacy applicants or within the last twenty-four (24) months for all other pharmacy applicants. If a state inspection is unavailable, an inspection by the Missouri Board of Pharmacy or from the Verified Pharmacy Program (VPP) of the National Association of State Boards of Pharmacy may be accepted.

(3) When requested to do so by the Missouri Board of Pharmacy, each nonresident pharmacy shall supply any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state in which it is located concerning the operation of a nonresident pharmacy—requested by the Board or the Board’s authorized designee to for review of compliance with state and federal drug laws.

(4) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state that licenses and regulates nonresident pharmacies for the purpose of investigating complaints against pharmacies located in Missouri or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.


20 CSR 2220-2.090 Pharmacist-in-Charge

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

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

(2) A pharmacist must immediately notify the Board electronically or in writing on a form designated by the Board if he/she stops serving as the designated pharmacist-in-charge. All controlled substances must be taken at or immediately prior to a pharmacist-in-charge change by both the outgoing pharmacist-in-charge and the incoming pharmacist-in-charge. The inventory must comply with all state and federal biennial inventory requirements, including, 21 CFR § 1304.11. The inventory must be signed by both the outgoing and incoming pharmacist-in-charge. If a joint inventory is not possible, the new pharmacist-in-charge and an official designee of the permit holder must complete, sign and date the inventory.

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


20 CSR 2220-2.950 Automated Filling Systems

PURPOSE: This rule establishes standards for automated filling systems.

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(A) “Automated filling system”—An automated system used by a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An “automated filling system” shall not include automated devices used solely to count medication, vacuum tube drug delivery systems governed by 20 CSR 2220-2.800, or automated dispensing and storage systems governed by 20 CSR 2220-2.900 used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient;

(B) “Electronic verification system”—An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system;

(C) “Manufacturer unit of use package”—A drug dispensed in the manufacturer’s original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label;

(D) “Repackager”—A repackager registered with the United States Food and Drug Administration; and

(E) “Repacked”—Any drug that has been removed from the original packaging of the manufacturer or a repackager’s packaging and is placed in a container for use in an automated filling system.

(2) Medication Stocking. Automated filling systems (hereinafter “system”) may be stocked or loaded by a pharmacist or by an intern pharmacist or pharmacy technician under the direct supervision of a pharmacist. Pharmacy repacked medication, cartridges, or containers shall comply with 20 CSR 2220-2.130.
(3) Verification. Except as provided herein, a licensed pharmacist shall inspect and verify the accuracy of the final contents of any medication filled or packaged by an automated filling system, and any label affixed thereto, prior to dispensing, as required by 20 CSR 2220-2.010(1)(B).

(4) The pharmacist verification requirements of section (3) shall be deemed satisfied if—
   (A) The pharmacy establishes and follows a policy and procedure manual that complies with section (5) of this rule;
   (B) The filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prescription is produced by the automated filling system that is ready for dispensing to the patient. No manual intervention with the medication or prescription may occur after the medication is loaded into the automated filling system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;
   (C) A pharmacist verifies the accuracy of the prescription information used by or entered into the automatic filling system for a specific patient prior to initiation of the automatic fill process. The name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy’s records and maintained for five (5) years after dispensing;
   (D) A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the automated filling system prior to initiating the fill process. Alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or repacked medication previously verified by a pharmacist;
   (E) The medication to be dispensed is filled, labeled, and sealed in the prescription container by the automated filling system or dispensed by the system in a manufacturer’s unit of use package or a repacked pharmacy container;
   (F) An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient; and
(G) Daily random quality testing is conducted by a pharmacist on a sample size of prescriptions filled by the automated filling system. The required sample size shall not be less than two percent (2%) of the prescriptions filled by the automated system on the date tested or two percent (2%) of the prescriptions filled by the automated system on the last day of system operation, as designated in writing by the pharmacist-in-charge. Alternatively, the pharmacy may test a sample size of filled prescriptions that has been determined to be statistically valid for assessing system accuracy. Proof of compliance with this subsection and random quality testing date(s) and results shall be documented and maintained in the pharmacy’s records.

(5) Policies and Procedures. Pharmacies verifying prescriptions pursuant to section (4) of this rule shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy’s records for a minimum of two (2) years. The required annual review shall be documented in the pharmacy’s records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for—

(A) Maintaining the automated filling system and any accompanying electronic verification system in good working order;

(B) Ensuring accurate filling, loading, and stocking of the system;

(C) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(D) Reporting, investigating, and addressing filling errors and system malfunctions;

(E) Testing the accuracy of the automated filling system and any accompanying electronic verification system. At a minimum, the automated filling system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the automated filling system or electronic verification system that changes or alters the filling or electronic verification process;

(F) Training persons authorized to access, stock, restock, or load the automated filling system in equipment use and operations;

(G) Tracking and documenting prescription errors related to the automated filling system that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for two (2) years and produced to the board upon request;
(H) Conducting routine and preventive maintenance and, if applicable, calibration;
(I) Removing expired, adulterated, misbranded, or recalled drugs;
(J) Preventing unauthorized access to the system, including assigning, discontinuing, or changing security access;
(K) Identifying and recording persons responsible for stocking, loading, and filling the system;
(L) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements; and
(M) Maintaining an ongoing quality assurance program that monitors performance of the automatic fill system and any electronic verification system to ensure proper and accurate functioning.

(6) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy’s records electronically or in writing for a minimum of two (2) years. When the verification requirements of subsection (4)(D) of this rule are completed by a pharmacist, the name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy’s records and maintained for five (5) years after dispensing. Records shall be made available for inspection and produced to the board or the board’s authorized designee upon request.
PURPOSE: This rule establishes procedures for pharmacists to administer medication pursuant to a medical prescription order.

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

(2) Except as otherwise provided by law, a pharmacist may not delegate medication administration to another person, except to an intern pharmacist who has met the qualifications of subsections (4)(B) – (D) and is working under the direct supervision of a pharmacist qualified to administer drugs by medical prescription order.

(3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the Board. To file a Notification of Intent, a pharmacist must—

(A) Hold a current Missouri pharmacist license;

(B) Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) certification or Basic Life Support certification issued by the American Heart Association, the American Red Cross or an equivalent organization. The certificate program must have included a live training component;

(C) Have successfully completed a certificate program in medication administration and emergency procedures accredited by the Accreditation Council for Pharmacy Education (ACPE) or provided by a governmental entity or a healthcare professional organization or educational institution approved by the Board. To obtain Board approval, the training program must [be taught by qualified instructors/a licensed healthcare professional and] provide instruction in:

1. Administration techniques which must include hands-on training in routes of administration;
2. Drug storage and handling;
3. Informed consent requirements;
4. Pre- and post-administration assessment and counseling;
5. Biohazard waste disposal, and;
6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks.

(D) Pharmacists shall maintain proof of compliance with the requirements of this section for a minimum of two (2) years.
(E) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist must first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of the required training and training date(s) must be maintained at the pharmacy and available to the Board on request.

(4) General Requirements.
   (A) Except as otherwise authorized by law, a pharmacist shall administer vaccines in accordance with current treatment guidelines established by the Centers for Disease Control and Prevention (CDC).
   (B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.
   (C) A pharmacist shall have a current and accurate written policy and procedure manual covering all aspects of administering drugs by medical prescription order. At a minimum, the required policies and procedures must include provisions governing:
      1. Drug administration procedures, including, authorized routes of administration,
      2. Drug storage;
      3. Pre- and post- administration assessment and counseling, including, providing vaccine information statements when applicable;
      4. Biohazard waste disposal and disposal of used/contaminated supplies;
      5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
      6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.
   (D) Drugs must be stored within the manufacturer's labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.
   (E) Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

(5) Requirements of Medical Prescription Order. At a minimum, the medical prescription order from a licensed prescriber must contain the following:
   (A) The name of the licensed prescriber issuing or authorizing the order;
   (B) The name of the patient to receive the drug;
   (C) The name of the drug and dose to be administered;
   (D) The route of administration;
   (E) The date of the original order; and
   (F) The date or schedule, if any, of each subsequent administration.

(6) Record Keeping.
(A) A pharmacist who administering medication pursuant to a medical prescription order must maintain the following records separate from the prescription files of a pharmacy:

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

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

(7) Notification Requirements.

(A) A pharmacist administering a vaccine pursuant to a medical prescription order shall notify the patient’s primary health care provider, if provided by the patient, within fourteen (14) days after administration of the following:

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

(B) In the event of any adverse event or reaction experienced by the patient following medication administration, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. Notification shall be mandatory and cannot be waived.
(C) A pharmacist administering drugs pursuant to a medical prescription order must report the administration to all entities as required by state or federal law. Pharmacist administered vaccines must also be reported to the Missouri immunization registry operated by the Missouri Department of Health and Senior Services (ShowMeVax), or its successor.

(D) Except as otherwise required by section (7)(C), notifications required by this section must be made electronically or in writing. Alternatively, notifications may be made via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Documentation of the required notifications, including the notification date, must be kept at the pharmacy or other authorized location where the prescription order is maintained.

(8) Notification of Intent Refiling. To continue administration, a Notification of Intent to administer drugs by medical prescription order must be refilled with the Board biennially along with the pharmacist’s Missouri pharmacist license. To refile, a pharmacist must:

(A) Hold a current Basic Life Support certification issued by the American Heart Association or the American Red Cross or an equivalent organization. The certification program must have included a live training component; and

(B) Have successfully completed four (4) hours of continuing education (0.4 CEU) related to administering drugs within the applicable pharmacist biennial renewal period between November 1st and October 31st of the immediately preceding even numbered years. The required continuing education (CE) shall be governed by 20 CSR 2220-7.080 and may be used to satisfy the pharmacist’s biennial pharmacist renewal CE requirements. The initial training program required by subsection (3) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within the applicable pharmacist biennial renewal cycle.


PURPOSE: This rule establishes the procedures for pharmacists to administer vaccines per written protocol with a physician.

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine. Unless otherwise restricted by the Board or the governing protocol, pharmacists authorized to immunize pursuant to this rule may administer immunizations at any Missouri licensed pharmacy. Immunizations may be provided at a non-pharmacy location if authorized by the governing protocol.

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

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

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

(D) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualifications under subsections (4)(B) and (C) and is working under the direct supervision of a pharmacist qualified to administer vaccines. Intern pharmacists must maintain proof of compliance with subsections (4)(B) and (C) for a minimum of two (2) years. (2) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.

(3) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, by protocol must:

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

(C) Have successfully completed a certificate program in administering vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy. To be approved, non-ACPE programs must include a live/in-person training component and include instruction in:

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

2. Basic immunology and vaccine protection;

3. Physiology and techniques for vaccine administration which must include hands-on training in common routes of vaccine administration, including, intramuscular, intradermal, subcutaneous and nasal routes of administration;

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

5. Identifying and treating adverse immunization reactions;

(D) Have filed a Notification of Intent with the Board of Pharmacy attesting that the pharmacist has complied with sections (3)(A) to (3)(C) of this rule. Notifications of Intent must be filed on the Board’s website or on a form approved by the Board; and

(E) Have a current written protocol with an authorizing physician that complies with this rule.

(4) Protocol Requirements.

(A) Pharmacists administering vaccines pursuant to this rule must enter into a written protocol with a Missouri licensed physician for the administration of vaccines as authorized by Chapter 338, RSMo. The written protocol may be valid for a time period not to exceed one (1) year and must be renewed annually. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;

2. Time period of the protocol;

3. The identification of the vaccines which may be administered;

4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
5. The identity of the authorized routes and anatomic sites of administration allowed;

6. A provision to create a prescription for each administration under the authorizing physician’s name;

7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;

8. A provision establishing the length of time the pharmacist shall observe an individual for adverse events following an injection;

9. A provision establishing the disposal of used and contaminated supplies;

10. The street addresses of any non-pharmacy locations at which the pharmacist may administer the authorized vaccine;

11. Record-keeping requirements and any required notification procedures; and

12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be manually or electronically signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

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

(5) Record Keeping.

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include:

1. The name, address, and date of birth of the patient;

2. The date, route, and anatomic site of the administration;

3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient’s primary health care provider, as identified by the patient;
5. The identity of the administering pharmacist or intern pharmacist;
6. The nature of an adverse reaction and who was notified, if applicable;
7. Documentation that pharmacist interns administering vaccines under the pharmacist’s supervision have complied with section (2) of this rule; and
8. Documentation that any notifications required by this rule have been sent.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection (5)(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(D) The records required by this rule shall be maintained securely and confidentially as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the pharmacy’s prescription files.
2. If the vaccine is not administered on behalf of a pharmacy, records shall be maintained securely and confidentially by the administering pharmacist at an address that must be identified in the protocol prior to administering the vaccine; and
3. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the State Board of Pharmacy and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.
(6) Notification of Immunizations. Notification of vaccine administration must comply with all state and federal law. All pharmacists provided immunizations must be reported to the Missouri immunization registry operated by the Missouri Department of Health and Senior Services (ShowMeVax). Additionally, pharmacists must comply with the following:

(A) Pharmacists shall notify the protocol physician after administering a vaccine as required by the governing protocol. Notification of vaccine administration must also be provided to the patient’s primary care provider as required by Chapter 338, RSMo.

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

(C) Unless otherwise provided by the governing protocol, notification may be made via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Proof of notification must be maintained in the pharmacist’s records as required by section (6) of this rule.

(7) Notification of Intent Renewal. A Notification of Intent (NOI) to immunize by protocol must be renewed biennially with the immunizing pharmacist’s Missouri pharmacist license. The NOI must be submitted on the Missouri Board of Pharmacy’s website or in a form approved by the Board. To renew a NOI, pharmacists must:

(A) Have a current Missouri pharmacist license;

(B) Have a current cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification that complies with section (4)(B) of this rule; and

(C) Have completed a minimum of two (2) hours of continuing education (0.2 CEU) related to administering vaccines or CDC immunization guidelines in a course provided by the Board or an ACPE accredited continuing education provider. Alternatively, continuing education may be provided by a governmental entity, healthcare professional organization or educational institution approved by the Board in advance. Approval requests for non-ACPE programs must be submitted in accordance with 20 CSR 2220-7.080. To be approved, non-ACPE programs must provide instruction in one or more of the following:
1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including, recommended immunization schedules;

2. Basic immunology and vaccine protection;

3. Physiology and techniques for vaccine administration;

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

5. Identifying and treating adverse immunization reactions.

(D) The required continuing education may be used to satisfy the pharmacist’s biennial continuing education requirements.
A9. Board Member Reports
#A10. General Administration Report

- Staff/Office Update
- Financial Report
- Board and Commissions Task Force
- 2017 Patient Safety Conference
- Bd. of Healing Arts Opioid Safety Conference
- 2017 Legislative Update
- Revised Board Brochures/Practice Guide
- NABP Sterile Compounding Blueprint Update
- Pending Rules
## Pharmacy

### FY 2017 YTD Financial Summary

**As of May 31, 2017**

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<th>FY 2017 Actual</th>
<th>FY 2017 Projections</th>
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### YTD Attorney's Services

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6/26/2017
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<th>YTD Expended</th>
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<th>Remaining Appropriation</th>
<th>Percent Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>140</td>
<td>TRAVEL, IN-STATE</td>
<td>27,372.31</td>
<td>25,000.00</td>
<td>(2,372.31)</td>
<td></td>
</tr>
<tr>
<td>160</td>
<td>TRAVEL, OUT-OF-STATE</td>
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<td>20,000.00</td>
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<tr>
<td>180</td>
<td>FUEL &amp; UTILITIES</td>
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<tr>
<td>190</td>
<td>SUPPLIES</td>
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<td>61,190.00</td>
<td>4,169.08</td>
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<tr>
<td>320</td>
<td>PROFESSIONAL DEVELOPMENT</td>
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<td>13,300.00</td>
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<tr>
<td>340</td>
<td>COMMUNICATION SERV &amp; SUPP</td>
<td>29,004.49</td>
<td>18,480.00</td>
<td>(10,524.49)</td>
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</tr>
<tr>
<td>400</td>
<td>PROFESSIONAL SERVICES</td>
<td>155,523.95</td>
<td>443,600.00</td>
<td>288,076.05</td>
<td>64.94%</td>
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<tr>
<td>420</td>
<td>HOUSEKEEP &amp; JANITOR SERV</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>430</td>
<td>M&amp;R SERVICES</td>
<td>6,721.45</td>
<td>13,000.00</td>
<td>6,278.55</td>
<td>48.30%</td>
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<tr>
<td>480</td>
<td>COMPUTER EQUIPMENT</td>
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<tr>
<td>560</td>
<td>MOTORIZED EQUIPMENT</td>
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<td>32,000.00</td>
<td>32,000.00</td>
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<tr>
<td>580</td>
<td>OFFICE EQUIPMENT</td>
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<td>3,000.00</td>
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<tr>
<td>590</td>
<td>OTHER EQUIPMENT</td>
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<td>0.00</td>
<td>(207.53)</td>
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<tr>
<td>640</td>
<td>PROPERTY &amp; IMPROVEMENTS</td>
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<td>5,000.00</td>
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<tr>
<td>680</td>
<td>BUILDING LEASE PAYMENTS</td>
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<td>3,000.00</td>
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<tr>
<td>690</td>
<td>EQUIPMENT RENTAL &amp; LEASES</td>
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<td>(891.63)</td>
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<tr>
<td>740</td>
<td>MISCELLANEOUS EXPENSES</td>
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<td>10,348.00</td>
<td>(12,443.73)</td>
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<tr>
<td>800</td>
<td>PROGRAM DISTRIBUTIONS</td>
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<td>18,814.67</td>
<td>94.07%</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td>334,153.05</td>
<td>668,418.00</td>
<td>334,264.95</td>
<td>50.01%</td>
</tr>
</tbody>
</table>
FY 2017 YTD Expenses by Budget Class Code
As of May 31, 2017
Pharmacy (0637)
Criminal History Checks: Approp 2586

<table>
<thead>
<tr>
<th>Budget Object Class</th>
<th>Budget Object Class Name</th>
<th>YTD Expended</th>
<th>Appropriation</th>
<th>Remaining Appropriation</th>
<th>Percent Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>400</td>
<td>PROFESSIONAL SERVICES</td>
<td>0.00</td>
<td>5,000.00</td>
<td>5,000.00</td>
<td>100.00%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>0.00</strong></td>
<td><strong>5,000.00</strong></td>
<td><strong>5,000.00</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>
## FY 2017 YTD Expenses by Budget Class Code
### As of May 31, 2017
#### Pharmacy (0637)

**Personal Service: Approp 3677**

<table>
<thead>
<tr>
<th>Budget Object Class</th>
<th>Budget Object Class Name</th>
<th>YTD Expended</th>
<th>Appropriation</th>
<th>Remaining Appropriation</th>
<th>Percent Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>SALARIES &amp; WAGES</td>
<td>949,993.48</td>
<td>1,089,799.00</td>
<td>139,805.52</td>
<td>12.83%</td>
</tr>
</tbody>
</table>

**TOTAL**

|               |             | 949,993.48   | 1,089,799.00 | 139,805.52              | 12.83%           |
GOVERNOR’S INITIAL SURVEY TO BOARDS/COMMISSIONS

Boards and Commission Survey

1. Name of the board/commission
2. Summary of what your board/commission does
3. Process Questions
   a. When was the last time your board/commission met?
   b. How do you set an agenda?
   c. Who has access to the agenda and minutes?
   d. When was the last time you had an action item?
   e. Do you have any action items pending?

4. Board Revenues and Expenditures
   a. How does your board/commission generate revenue?
   b. How much are your expenditures?
   c. Do you share staff with another board/commission? If so, how much staff time is spent on your board?

5. Does your board/commission administer Federal funds/grants?

6. What safety does your board/commission provide to the public?

7. Any board/commission that would be a natural consolidation? If you believe there is no way to consolidate why not?

8. Do you think your board/commission would be better served with less members? Why/why not?
AN ACT

To repeal sections 208.227, 208.790, 208.798, and 334.506, RSMo, and to enact in lieu thereof eight new sections relating to health care.

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

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

196.990. 1. As used in this section, the following terms shall mean:

(1) "Administer", the direct application of an epinephrine auto-injector to the body of an individual;

(2) "Authorized entity", any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas. "Authorized entity" shall not include any public school or public charter school;

(3) "Epinephrine auto-injector", a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;

(4) "Physician", a physician licensed in this state under chapter 334;

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.
(5) "Provide", the supply of one or more epinephrine auto-injectors to an individual;

(6) "Self-administration", a person's discretionary use of an epinephrine auto-injector.

2. A physician may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists, physicians, and other persons authorized to dispense prescription medications may dispense epinephrine auto-injectors under a prescription issued in the name of an authorized entity.

3. An authorized entity may acquire and stock a supply of epinephrine auto-injectors under a prescription issued in accordance with this section. Such epinephrine auto-injectors shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use and any additional requirements established by the department of health and senior services by rule. An authorized entity shall designate employees or agents who have completed the training required under this section to be responsible for the storage, maintenance, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

4. An authorized entity that acquires a supply of epinephrine auto-injectors under a prescription issued in accordance with this section shall ensure that:

   (1) Expected epinephrine auto-injector users receive training in recognizing symptoms of severe allergic reactions including anaphylaxis and the use of epinephrine auto-injectors from a nationally recognized organization experienced in training laypersons in emergency health treatment or another entity or person approved by the department of health and senior services;

   (2) All epinephrine auto-injectors are maintained and stored according to the epinephrine auto-injector's instructions for use;

   (3) Any person who provides or administers an epinephrine auto-injector to an individual who the person believes in good faith is experiencing anaphylaxis activates the emergency medical services system as soon as possible; and

   (4) A proper review of all situations in which an epinephrine auto-injector is used to render emergency care is conducted.

5. Any authorized entity that acquires a supply of epinephrine
auto-injectors under a prescription issued in accordance with this section shall notify the emergency communications district or the ambulance dispatch center of the primary provider of emergency medical services where the epinephrine auto-injectors are to be located within the entity's facility.

6. No person shall provide or administer an epinephrine auto-injector to any individual who is under eighteen years of age without the verbal consent of a parent or guardian who is present at the time when provision or administration of the epinephrine auto-injector is needed. Provided, however, that a person may provide or administer an epinephrine auto-injector to such an individual without the consent of a parent or guardian if the parent or guardian is not physically present and the person reasonably believes the individual shall be in imminent danger without the provision or administration of the epinephrine auto-injector.

7. The following persons and entities shall not be liable for any injuries or related damages that result from the administration or self-administration of an epinephrine auto-injector in accordance with this section that may constitute ordinary negligence:

1. An authorized entity that possesses and makes available epinephrine auto-injectors and its employees, agents, and other trained persons;

2. Any person who uses an epinephrine auto-injector made available under this section;

3. A physician that prescribes epinephrine auto-injectors to an authorized entity; or

4. Any person or entity that conducts the training described in this section.

Such immunity does not apply to acts or omissions constituting a reckless disregard for the safety of others or willful or wanton conduct. The administration of an epinephrine auto-injector in accordance with this section shall not be considered the practice of medicine. The immunity from liability provided under this subsection is in addition to and not in lieu of that provided under section 537.037. An authorized entity located in this state shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or
agents outside of this state if the entity or its employee or agent is not liable for such injuries or related damages under the laws of the state in which such provision or administration occurred. No trained person who is in compliance with this section and who in good faith and exercising reasonable care fails to administer an epinephrine auto-injector shall be liable for such failure.

8. All basic life support ambulances and stretcher vans operated in the state shall be equipped with epinephrine auto-injectors and be staffed by at least one individual trained in the use of epinephrine auto-injectors.

9. The provisions of this section shall apply in all counties within the state and any city not within a county.

10. Nothing in this section shall be construed as supersed ing the provisions of section 167.630.

208.227. [Fee for service eligible policies for prescribing psychotropic medications shall not include any new limits to initial access requirements, except dose optimization or new drug combinations consisting of one or more existing drug entities or preference algorithms for SSRI antidepressants, for persons with mental illness diagnosis, or other illnesses for which treatment with psychotropic medications are indicated and the drug has been approved by the federal Food and Drug Administration for at least one indication and is a recognized treatment in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature and deemed medically appropriate for a diagnosis.] 1. No restrictions to access shall be imposed that preclude availability of any individual atypical antipsychotic monotherapy for the treatment of schizophrenia, bipolar disorder, or psychosis associated with severe depression. The division shall establish a pharmaceutical case management or polypharmacy program for high-risk MO HealthNet participants with numerous or multiple prescribed drugs. The division shall also establish a behavioral health pharmacy and opioid surveillance program to encourage the use of best medical evidence-supported prescription practices. The division shall communicate with providers, as such term is defined in section 208.164, whose prescribing practices deviate from or do not otherwise utilize best medical evidence-supported prescription practices. The communication may be telemetric, written, oral, or some combination thereof. These programs
shall be established and administered through processes established and supported under a memorandum of understanding between the department of mental health and the department of social services, or their successor entities.

2. The provisions of this section shall not prohibit the division from utilizing clinical edits to ensure clinical best practices including, but not limited to:

   (1) Drug safety and avoidance of harmful drug interactions;
   (2) Compliance with nationally recognized and juried clinical guidelines from national medical associations using medical evidence and emphasizing best practice principles;
   (3) Detection of patients receiving prescription drugs from multiple prescribers; and
   (4) Detection, prevention, and treatment of substance use disorders.

3. The division shall issue a provider update no less than twice annually to enumerate treatment and utilization principles for MO HealthNet providers including, but not limited to:

   (1) Treatment with antipsychotic drugs, as with any other form of treatment, should be individualized in order to optimize the patient's recovery and stability;
   (2) Treatment with antipsychotic drugs should be as effective, safe, and well-tolerated as supported by best medical evidence;
   (3) Treatment with antipsychotic drugs should consider the individual patient's needs, preferences, and vulnerabilities;
   (4) Treatment with antipsychotic drugs should support an improved quality of life for the patient;
   (5) Treatment choices should be informed by the best current medical evidence and should be updated consistent with evolving nationally recognized best practice guidelines; and
   (6) Cost considerations in the context of best practices, efficacy, and patient response to adverse drug reactions should guide antipsychotic medication policy and selection once the preceding principles have been maximally achieved.

4. If the division implements any new policy or clinical edit for an antipsychotic drug, the division shall continue to allow MO HealthNet participants access to any antipsychotic drug that they
utilize and on which they are stable or that they have successfully utilized previously. The division shall adhere to the following:

(1) If an antipsychotic drug listed as "nonpreferred" is considered clinically appropriate for an individual patient based on the patient's previous response to the drug or other medical considerations, prior authorization procedures, as such term is defined in section 208.164, shall be simple and flexible;

(2) If an antipsychotic drug listed as "nonpreferred" is known or found to be safe and effective for a given individual, the division shall not restrict the patient's access to that drug. Such nonpreferred drug shall, for that patient only and if that patient has been reasonably adherent to the prescribed therapy, be considered "preferred" in order to minimize the risk of relapse and to support continuity of care for the patient;

(3) A patient shall not be required to change antipsychotic drugs due to changes in medication management policy, prior authorization, or a change in the payor responsible for the benefit; and

(4) Patients transferring from state psychiatric hospitals to community-based settings, including patients previously found to be not guilty of a criminal offense by reason of insanity or who have previously been found to be incompetent to stand trial, shall be permitted to continue the medication regimen that aided the stability and recovery so that such patient was able to successfully transition to the community-based setting.

5. The division's medication policy and clinical edits shall provide MO HealthNet participants initial access to multiple Food and Drug Administration-approved antipsychotic drugs that have substantially the same clinical differences and adverse effects that are predictable across individual patients and whose manufacturers have entered into a federal rebate agreement with the Department of Health and Human Services. Clinical differences may include, but not be limited to, weight gain, extrapyramidal side effects, sedation, susceptibility to metabolic syndrome, other substantial adverse effects, the availability of long-acting formulations, and proven efficacy in the treatment of psychosis. The available drugs for an individual patient shall include, but not be limited to, the following categories:

(1) At least one relatively weight-neutral atypical antipsychotic
medication;
(2) At least one long-acting injectable formulation of an atypical antipsychotic;
(3) Clozapine;
(4) At least one atypical antipsychotic medication with relatively potent sedative effects;
(5) At least one medium-potency typical antipsychotic medication;
(6) At least one long-acting injectable formulation of a high-potency typical antipsychotic medication;
(7) At least one high-potency typical antipsychotic medication; and
(8) At least one low-potency typical antipsychotic medication.

6. Nothing in subsection 5 of this section shall be construed to require any of the following:
(1) Step therapy or a trial of a typical antipsychotic drug before permitting a patient access to an atypical drug or antipsychotic medication;
(2) A limit of one atypical antipsychotic drug as an open-access, first-choice agent; or
(3) A trial of one of the eight categories of drugs listed in subsection 5 of this section before having access to the other seven categories.

7. The department of social services may promulgate 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, 2017, shall be invalid and void.

8. The department shall submit such state plan amendments and waivers to the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services as the department
determines are necessary to implement the provisions of this section.

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

(1) "Division", the MO HealthNet division of the department of social services;

(2) "Reasonably adherent", a patient's adherence to taking medication on a prescribed schedule as measured by a medication position ratio of at least seventy-five percent;

(3) "Successfully utilized previously", a drug or drug regimen's provision of clinical stability in treating a patient's symptoms.

208.229. 1. Pharmaceutical manufacturers shall pay to the state, in accordance with 42 U.S.C. Section 1396r-8, rebates on eligible utilization of covered outpatient drugs dispensed to MO HealthNet participants under the MO HealthNet pharmacy program as follows:

(1) For single source drugs and innovator multiple source drugs, rebates shall reflect the manufacturer's best price, as defined by 42 CFR 447.505, as updated and amended, and set forth in 42 CFR 447.509, as updated and amended; and

(2) For single source drugs and innovator and noninnovator multiple source drugs, any additional rebates necessary to account for certain price increases in excess of inflation, as set forth in 42 CFR 447.509, as updated and amended.

2. For purposes of this section, the terms "innovator multiple source drug", "noninnovator multiple source drug", and "single source drug" shall have the same meanings as defined in 42 CFR 447.502, as updated and amended.

208.790. 1. The applicant shall have or intend to have a fixed place of residence in Missouri, with the present intent of maintaining a permanent home in Missouri for the indefinite future. The burden of establishing proof of residence within this state is on the applicant. The requirement also applies to persons residing in long-term care facilities located in the state of Missouri.

2. The department shall promulgate rules outlining standards for documenting proof of residence in Missouri. Documents used to show proof of residence shall include the applicant's name and address in the state of Missouri.

3. Applicant household income limits for eligibility shall be subject to appropriations, but in no event shall applicants have household income that is greater than one hundred eighty-five percent of the federal poverty level for the applicable family size for the applicable year as converted to the MAGI equivalent
13 net income standard. The provisions of this subsection shall only apply
to Medicaid dual eligible individuals.

4. The department shall promulgate rules outlining standards for
4 documenting proof of household income.

208.798. The provisions of sections 208.780 to 208.798 shall terminate on

334.506. 1. As used in this section, "approved health care provider"
means a person holding a current and active license as a physician and surgeon
under this chapter, a chiropractor under chapter 331, a dentist under chapter
332, a podiatrist under chapter 330, a physician assistant under this chapter, an
advanced practice registered nurse under chapter 335, or any licensed and
registered physician, chiropractor, dentist, or podiatrist practicing in another
jurisdiction whose license is in good standing.

2. A physical therapist shall not initiate treatment for a new injury or
illness without a prescription from an approved health care provider.

3. A physical therapist may provide educational resources and training,
develop fitness or wellness programs for asymptomatic persons, or provide
screening or consultative services within the scope of physical therapy practice
without the prescription and direction of an approved health care provider.

4. A physical therapist may examine and treat without the prescription
and direction of an approved health care provider any person with a recurring
self-limited injury within one year of diagnosis by an approved health care
provider or a chronic illness that has been previously diagnosed by an approved
health care provider. The physical therapist shall:

(1) Contact the patient's current approved health care provider within
seven days of initiating physical therapy services under this subsection;

(2) Not change an existing physical therapy referral available to the
physical therapist without approval of the patient's current approved health care
provider;

(3) Refer to an approved health care provider any patient whose medical
condition at the time of examination or treatment is determined to be beyond the
scope of practice of physical therapy;

(4) Refer to an approved health care provider any patient whose condition
for which physical therapy services are rendered under this subsection has not
been documented to be progressing toward documented treatment goals after six
visits or fourteen days, whichever first occurs;
(5) Notify the patient’s current approved health care provider prior to the continuation of treatment if treatment rendered under this subsection is to continue beyond thirty days. The physical therapist shall provide such notification for each successive period of thirty days.

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

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

7. A physical therapist shall only delegate physical therapy treatment to a physical therapist assistant or to a person in an entry level of a professional education program approved by the Commission on Accreditation of Physical Therapy Education who satisfies supervised clinical education requirements related to the person’s physical therapist or physical therapist assistant education. The entry-level person shall be under on-site the supervision of a physical therapist.

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

(1) "Board", the Missouri board of pharmacy;

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

(3) "Program", the RX cares for Missouri program.

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

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

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

4. After a full year of program operation, the board shall prepare and submit an evaluation report to the governor and the general assembly describing the operation of the program and the funds allocated. Unless otherwise authorized by the general assembly, the program shall expire on August 28, 2019.
#A11. Inspection/Investigation Report

- Inspection/Investigation Updates
#A12. Hospital Advisory Committee Update

- Chairman Updates
- Update on Class-B Hospital Guidance
#A13. *Sterile Compounding Committee Update*
#A14. Fiscal Year 2018-2019 Strategic Plan
INTRODUCTION:

In 2016, the Missouri Board of Pharmacy initiated a strategic review of Board operations facilitated by AHC Consulting, LLC. A public strategic planning meeting was held on July 19, 2016, followed by a public strategic planning discussion on April 18, 2017.

The following strategic planning report has been approved by the Board for FY 18-19. The Board looks forward to continuing its efforts to protect Missouri citizens by promoting, enhancing and ensuring patient safety.

BOARD HISTORY:

The Missouri Board of Pharmacy was established in 1909 and is an autonomous Board within the Division of Professional Registration, an agency of the Missouri Department of Insurance, Financial Institutions and Professional Registration.

The Board consists of seven (7) members, including one (1) public member and six (6) licensed pharmacists actively engaged in the practice of pharmacy in Missouri. By statute, at least one board member must be a person who provides pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. All members are appointed by the Governor and confirmed by the Missouri Senate. Members hold office for five years and until their successors have been appointed and confirmed.

MISSION:

The mission of the Board of Pharmacy is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetency, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
- Licenses only "qualified" professionals by examination and evaluation of minimum competency, and;
- Enforces regulatory standards by implementing legislation and administrative rules.

STRENGTHS:

The Board continues to expand its efforts to advance its regulatory goals. Current strengths include:

- Proactive educational tools, resources and webinars
- An open, transparent Board culture that invites and includes key stakeholder participation and input
- Diverse experience and expertise among Board members
- Fiscal responsibility
- Positive relationships and engagement with state pharmacy organizations

**REGULATORY CHALLENGES:**

The Board identified the following regulatory challenges:
- Lengthy rulemaking process which delays addressing regulatory needs/challenges and other regulatory changes in a prompt manner (e.g., technological advances)
- Board member vacancies and expired terms
- Addressing and accommodating evolving pharmacy technician practice
- Effectively communicating with diverse stakeholders and licensees

**STRATEGIC GOALS:**

**GOAL # 1: Provide clear rules and regulations**

<table>
<thead>
<tr>
<th>Performance Measure</th>
<th>Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update Board rules to incorporate technician training and education requirements and modernize technician practice</td>
<td></td>
</tr>
</tbody>
</table>

**GOAL # 2: Expand Board impact through strategic alliances with relevant stakeholders to enhance the practice of pharmacy in Missouri and increase stakeholder engagement.**

<table>
<thead>
<tr>
<th>Performance Measure</th>
<th>Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consult with public relations professional to review current Board communication activities and identify ways to enhance communication efforts to expand population reach and engagement</td>
<td></td>
</tr>
</tbody>
</table>
GOAL # 3: Promote and enhance career and skill development for board management and staff.

<table>
<thead>
<tr>
<th>Performance Measure</th>
<th>Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pursue salary increases to increase retention and maintain institutional resources/expertise</td>
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GOAL # 4: Leverage technology and available resources to increase and enhance communication to licensees and relevant stakeholders.

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<tr>
<th>Performance Measure</th>
<th>Benchmark</th>
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#A15. Discussion of Remote Technician Supervision/Remote Medication Verification
## Telepharmacy Rules and Statutes: A 50-State Survey

### Table Supplement to Brief No. 2017-4

**State Restrictions of Telepharmacy where Legislatively or Administratively Authorized, August 2016**

<table>
<thead>
<tr>
<th>State</th>
<th>Geographic Restrictions</th>
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<th>Inter-State Accessibility</th>
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<tr>
<td>Alaska</td>
<td>Located at least 10 road miles from any non-remote pharmacy unless federal law prohibits non-remote pharmacy from providing pharmacy services to individuals within the area. (12 AAC 52.423(b)(2))</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist, pharmacy technician, pharmacy intern. (12 AAC 52.425 (c)(1))</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
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<tr>
<td>Colorado</td>
<td>Located at least 20 miles from any pharmacy or telepharmacy outlet. (12-42.5-102(39.5)(a)(ii))</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist; pharmacy technician. (12-42.5-102(39.5)(a)(IV))</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
</tr>
<tr>
<td>Hawaii</td>
<td>Located at least 5 miles from any pharmacy except for remote dispensing pharmacy established prior to July 3, 2008 that has previously dispensed and will continue to dispense only prescription medications acquired pursuant to section 340B of the Public Health Service Act, Title 42 United States Code section 256b. (§461-10.5(c)(1))</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist; qualified remote dispensing technician. §461-10.5(a)(2)</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
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| Idaho   | 1) The Board will consider the availability of pharmacists, the population of the community, and the community’s need for the service.  
  2) The Board will not approve a remote dispensing site if a retail pharmacy is located within the same community as the proposed remote dispensing site. (27.01.01 -710.01) | Remote dispensing site must be located in a medical care facility operating in areas otherwise unable to obtain pharmaceutical care services on a timely basis. (27.01.01 -710.01(c)) | Pharmacist; pharmacist technician. (27.01.01 -710.05)                                      | 1) Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least 1 certified technician with at least 2,000 hours pharmacy technician experience in Idaho and under the supervision of a pharmacist at the supervising pharmacy when the remote site is open.  
  2) Supervision does not require physical presence by a pharmacist, but the pharmacist must supervise electronically from the supervising pharmacist | Not telepharmacy specific. |
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<tr>
<td>Illinois</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist, pharmacist technician. (1330.510(8)(A))</td>
<td>1) Remote pharmacy technician must have 1 year of experience and be registered as a certified pharmacy technician, or be a student pharmacist. 2) Hub pharmacists may electronically supervise no more than 3 simultaneously open remote sites. (1330.510(8)(A)&amp;(C))</td>
<td>1) Hub pharmacies located outside Illinois must be licensed as a nonresident pharmacy. 2) Nonresident pharmacies shall abide by all Illinois laws, except that dispensing pharmacist and the pharmacist-in-charge shall not require Illinois licensure. (1330.510(a))</td>
</tr>
<tr>
<td>Indiana</td>
<td>Not telepharmacy specific.</td>
<td>Telepharmacies can be Category I (retail), Category II (institutional), or Category III (processing) permits. (IC 25-26-13-17(b))</td>
<td>Pharmacist, pharmacy technician, pharmacy intern. (IC 25-26-13-18.5)</td>
<td>A pharmacist may not supervise more than 6 pharmacy technicians/pharmacy technicians in training. IC 25-26-13-18.5(c)</td>
<td>Not telepharmacy specific.</td>
</tr>
<tr>
<td>Iowa</td>
<td>A remote dispensing site will not be approved if a general pharmacy is located within the same community or is located within 15 miles of the proposed remote dispensing site. (IAC 657—9.5(124,155A)(2)(c))</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist; Pharmacy technician; pharmacist intern. (IAC 657—9.3(147,155A)(2)(f))</td>
<td>1) A remote dispensing site must be staffed by one or more qualified certified pharmacy technicians under the supervision of a pharmacist at the managing pharmacy when the remote site is open. 2) Continuous supervision does not require physical presence by the pharmacist, but the pharmacist must supervise electronically through the automated pharmacy system. (IAC 657—9.18(124,155A)(2))</td>
<td>Not telepharmacy specific.</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Must be located at least 20 miles (driving distance) from any other pharmacy. (§2425.(A)(1))</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist; pharmacy technician. (§2425.(E)(2)(c))</td>
<td>1) At a minimum, the site must be staffed by a Louisiana-licensed certified pharmacy technician with at least two years of experience as a Louisiana-licensed certified pharmacy technician and with demonstrated proficiency in operating the telepharmacy system being used. 2) In the absence of a pharmacist, the</td>
<td>A central pharmacy may supervise no more than two telepharmacy dispensing sites, and all such sites must be located within Louisiana. (§2425.(A)(5))</td>
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Notes:
- Geographic Restrictions
  - Illinois: Not telepharmacy specific.
  - Indiana: Not telepharmacy specific.
  - Iowa: Not telepharmacy specific.
  - Louisiana: Must be located at least 20 miles (driving distance) from any other pharmacy. (§2425.(A)(1))
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| Minnesota 1 | Medically underserved community.                                                        | Not telepharmacy specific.                           | Pharmacist, pharmacy technician                          | 1) All remote sites are staffed with Minnesota registered pharmacy technicians.  
2) Pharmacy technicians working at a remote site must have a minimum of 1 year (2080 hours) of experience as a registered technician and be certified through a Board-approved program. | Not telepharmacy specific.                |
| Montana     | Cannot be located within 25 mile radius of an existing pharmacy. (24.174.1302(2))       | Not telepharmacy specific.                           | Pharmacist; pharmacy technician. (24.174.1302(4)(a))     | 1) The remote site must be staffed by registered pharmacy technician.  
2) The technician must have at least 500 hours experience. (24.174.1302(4)(a)&(b))                                                                 | Not telepharmacy specific.                |
| Nebraska 2  | Must be located 1) At least 50 miles or more from the nearest pharmacy; and 2) In a service area with a total population of less than 2,000. (NRS 639.23277(1)(a)&(b)) | Not telepharmacy specific.                           | Pharmacist, pharmaceutical technician, dispensing technician. (NRS 639.23277(2)(a)&(b)) | A remote/satellite consultation site may be operated by:  
1) A pharmaceutical technician without the physical presence of a managing pharmacist, but the managing pharmacist of the telepharmacy shall also be deemed the managing pharmacist of the remote/satellite consultation site; or  
2) A dispensing technician without the physical presence of a dispensing practitioner, but the dispensing practitioner of the telepharmacy shall also be deemed the managing pharmacist of the remote/satellite consultation site. (NRS 639.23277(2)(a)&(b)) | Not telepharmacy specific.                |
| Nevada      | Must be located greater than 25 miles from an existing community pharmacy. (16.19.33.2) | Not telepharmacy specific.                           | Pharmacist; pharmacist technician. (16.19.33.7(J))       | Tele-pharmacy technician must have a minimum of 2,000 hours of experience as a certified registered pharmacy technician and can be supervised under the computer aided supervision of an | Both the hub pharmacy and all remote tele-pharmacies must be located within New Mexico. (16.19.33.2) |

1 These restrictions are based on Minnesota’s Board of Pharmacy “Guidance” on Variances for telepharmacies, not rules or statutes. Therefore, these are not rigid requirements.

2 Nebraska currently has legislative approval to authorize telepharmacy, although no board rules have yet been implemented regulating telepharmacy. See §38-2845.01.
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<td><strong>North Dakota</strong></td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist; pharmacy technician. (61-02-01-01(4)(k))</td>
<td>1) Technician must have at least 1 year of work experience as a North Dakota-registered pharmacy technician. 2) The technician must be a graduate of an approved pharmacy technician education program and must demonstrate proficiency in preparation of prescriptions for dispensing to patients. 3) A pharmacist may not supervise more than four telepharmacy sites. (61-02-08-04.(1)(a)&amp;(b)&amp;(c))</td>
<td>Both the central pharmacy and remote site may be located within North Dakota, either the remote site or the central pharmacy, may be located in a contiguous state. (61-02-08-01.(4))</td>
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<tr>
<td><strong>Oregon</strong></td>
<td>Not telepharmacy specific.</td>
<td>Telepharmacy limited to Remote Dispensing Facility (RDF), a facility where drugs are prepared for administration and where requisite pharmacist supervision is provided remotely as approved by the Board. (855-041-4100(2)) &amp; (855-041-4200)</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
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<tr>
<td><strong>South Dakota</strong></td>
<td>Demonstrated limitation on access to pharmacy services within the community. (20:51:30:02.)</td>
<td>Any pharmacy licensed by the board may operate a remote pharmacy in South Dakota. The remote pharmacy is considered an extension of the central pharmacy but the remote pharmacy must have its own license as a pharmacy. (20:51:30:06.)</td>
<td>Pharmacist, pharmacy technician, pharmacy intern. (20:51:30:12.)</td>
<td>1) Pharmacy technician must have at least 2000 hours of experience as a registered pharmacy technician. 2) Pharmacy intern must have at least 500 hours of experience as a registered pharmacy intern. 3) The pharmacist on duty at a central pharmacy may supervise no more than 3 technicians (a pharmacy intern does not count towards this ratio). 4) The total number of allowed technicians may be divided between the central pharmacy and the remote pharmacy in any manner. However, each remote pharmacy must have at least one pharmacy technician or pharmacy intern on duty while open. (20:51:30:12.) &amp; (20:51:30:13.)</td>
<td>Not telepharmacy specific.</td>
</tr>
<tr>
<td><strong>Tennessee</strong></td>
<td>1) Central pharmacy must be located</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist-in-charge</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
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in Federally Qualified Health Center that is connected through computer link, video link, and audio link to one or more satellite clinics. (§ 63-10-601)

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<td>Texas</td>
<td>1) A provider pharmacy may not provide remote pharmacy services if a Class A (Community) or Class C (Institutional) pharmacy that dispenses prescription drug orders to out-patients is located in the same community. 2) Community is defined as: (a) the census tract in which the remote site is located, if the remote site is located in a Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most recent U.S. Census; or (b) within 10 miles of the remote site, if the remote site is not located in a MSA. (§291.121(c)(3)(B)(i)&amp;(ii))</td>
<td>A provider pharmacy may provide remote pharmacy services using a telepharmacy system to: 1) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended; 2) a health center as defined by 42 U.S.C. Section 254b, as amended; or 3) a healthcare facility located in a medically underserved area as defined by state or federal law. (§291.121(c)(3)(A)(i)&amp;(ii) &amp; (iii))</td>
<td>Pharmacist, pharmacy technician, pharmacy technician trainee. (§291.121(F)(i)(i))</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
</tr>
<tr>
<td>Vermont</td>
<td>Remote pharmacy must be at least a 10 mile drive away from a retail pharmacy. (19.7(c))</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist, certified pharmacy technician, pharmacy intern. (19.11(a))</td>
<td>1) Remote pharmacies shall be staffed by certified pharmacy technicians under the continuous supervision of a pharmacist. 2) Certified pharmacy technicians must have a minimum of 2,000 hours experience as a registered pharmacy technician. 3) Pharmacy interns may not work at a remote pharmacy unless a pharmacist is physically present at the remote pharmacy. 19.2(a)(4); 19.11(b)&amp;(c)</td>
<td>A pharmacist providing telepharmacy services into Vermont from another state is required to register as an &quot;out of state registered pharmacist&quot; with the Board. (2.9(a))</td>
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<tr>
<td>State</td>
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<td>Virginia</td>
<td>Not telepharmacy specific.</td>
<td>A remote dispensing site can be located at: 1) A health care facility; 2) The office or clinic of a practitioner; 3) A county jail, rehabilitation facility state prison or county house of correction; 4) A juvenile correctional facility, juvenile detention facility, residential care center for children and youth, secured residential care center for children and youth, type 1 juvenile correctional facility, type 2 residential care center for children and youth, or type 2 juvenile correctional facility. (7.095(3)(a)&amp;(b)&amp;(c)&amp;(d))</td>
<td>Pharmacist, pharmacy technician, pharmacy intern. (7.095(7))</td>
<td>Pharmacy technician must have completed 1500 hours of work as a technician within the 3 years prior to working at the remote dispensing site or completed a board-approved training program. (7.095(7)(c))</td>
<td>Not telepharmacy specific.</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Not telepharmacy specific.</td>
<td>1) A health care facility; 2) The office or clinic of a practitioner; 3) A county jail, rehabilitation facility state prison or county house of correction; 4) A juvenile correctional facility, juvenile detention facility, residential care center for children and youth, secured residential care center for children and youth, type 1 juvenile correctional facility, type 2 residential care center for children and youth, or type 2 juvenile correctional facility. (7.095(3)(a)&amp;(b)&amp;(c)&amp;(d))</td>
<td>Pharmacist, pharmacy technician, pharmacy intern. (7.095(7))</td>
<td>Pharmacy technician must have completed 1500 hours of work as a technician within the 3 years prior to working at the remote dispensing site or completed a board-approved training program. (7.095(7)(c))</td>
<td>Not telepharmacy specific.</td>
</tr>
<tr>
<td>Wyoming</td>
<td>Must be located at least 25 miles from any retail pharmacy. (14.3(g))</td>
<td>Not telepharmacy specific.</td>
<td>Pharmacist, pharmacy technician, pharmacy intern. (14.5(b))</td>
<td>Not telepharmacy specific.</td>
<td>Not telepharmacy specific.</td>
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This project was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1C RH20149, Rural Health Research Center Cooperative Agreement to the RUPRI Center for Rural Health Policy Analysis. This study was 100% funded from governmental sources. This information or content and conclusions are those of the authors and should not be construed as the official position or policy of, nor should any endorsements be inferred by, HRSA, HHS, or the U.S. Government.

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E-mail: cph-rupri-inquiries@uiowa.edu

3 West Virginia currently has legislative approval to authorize telepharmacy, although no board rules have yet been implemented regulating telepharmacy. See §15-1-28.
CHAPTER 40
TECH-CHECK-TECH PROGRAMS

657—40.1(155A) Purpose and scope. The board may authorize a hospital pharmacy to participate in a tech-check-tech program. The board may authorize a general pharmacy providing pharmaceutical services to patients in a long-term care facility as defined herein to participate in a tech-check-tech (TCT) program for dispensing only to patients in the long-term care facility. The purpose of the tech-check-tech program is to authorize certified pharmacy technicians to review the work of other certified pharmacy technicians in connection with the filling of floor stock, including automated medication distribution systems (AMDS) and unit dose dispensing systems for institutionalized patients whose orders have previously been reviewed and approved by a licensed pharmacist, for the purpose of redirecting and optimizing pharmacist patient care services. Implementation of a tech-check-tech program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of the pharmacist for involvement in cognitive and patient care activities.

[ARC 9783B, IAB 10/5/11, effective 11/9/11]

657—40.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“Automated medication distribution system” or “AMDS” includes, but is not limited to, an automated device or series of devices operated by an electronic interface with one or more computers that is used to prepare, package, or dispense specified dosage units of drugs for administration or dispensing to a patient or the ultimate user. “AMDS” includes a device that prepares and packages a drug for unit dose dispensing, that prepares and packages a drug into outpatient prescription vials, and that dispenses prepackaged drugs.

“Board” means the board of pharmacy.

“Certified medication aide” means an individual who has successfully completed a medication aide course approved by the Iowa department of inspections and appeals or who has passed a medication aide challenge examination approved by the Iowa department of inspections and appeals and administered by an area community college. A “certified medication aide” is not a “licensed health care professional” as that term is used herein.

“Certified pharmacy technician” means an individual who holds a valid current national certification and who has registered with the board as a certified pharmacy technician pursuant to 657—Chapter 3.

“Checking technician” means a certified pharmacy technician who has been authorized by the pharmacist in charge to participate in a TCT program by checking the work of other certified pharmacy technicians.

“Component” means any single physical or electronic storage or access device that, in combination with other devices, makes up an AMDS.

“Drug bin” means a compartment in an AMDS component that is designed to contain one specific drug.

“Floor stock” means a supply of drugs consisting of emergency drugs and controlled substances that are routinely maintained on patient care units and accessible by nursing staff for patient administration.

“Hospital pharmacy” means a pharmacy licensed by the board pursuant to 657—Chapter 7 and located within a facility which is primarily engaged in providing, by or under the supervision of physicians, concentrated medical and nursing care on a 24-hour basis to inpatients and which maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses.

“Long-term care facility” means a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients and which is registered by the board for controlled substances under Iowa Code chapter 124.

“Medication order” means a written or electronic order from a practitioner or an oral order from a practitioner or the practitioner’s authorized agent for administration of a drug or device and, for purposes of this chapter, includes a prescription drug order.

“TCT program” means a board-approved tech-check-tech program implemented and formally established pursuant to these rules by the pharmacist in charge who has determined that one or more
certified pharmacy technicians are qualified to safely check the work of other certified pharmacy technicians and thereby provide final verification of drugs which are dispensed for subsequent administration to patients in an institutional setting.

“Unit dose dispensing system” means a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from patient care areas, enables the selection and distribution of drugs to be pharmacy-based and controlled, and improves accountability and accuracy.

[ARC 9783B, IAB 10/5/11, effective 11/9/11]

657—40.3(155A) General requirements. To participate in a TCT program, a hospital pharmacy shall be located in Iowa and provide pharmaceutical services to patients receiving treatment in a hospital located in Iowa. To participate in a TCT program, a general pharmacy shall be located in Iowa, and a TCT program shall only be implemented to provide pharmaceutical services to patients in a long-term care facility located in Iowa.

40.3(1) Site-specific. A TCT program shall be specific to the site at which implementation of the program is proposed and shall include a site-specific training program tailored to the patient population and the drug distribution system utilized.

40.3(2) Plan approval. At least 90 days prior to anticipated implementation of a TCT program, the pharmacist in charge shall submit the program plan, consistent with the requirements of these rules, for board approval. A pharmacy shall not implement a TCT program prior to receipt of notification that the board has approved the submitted TCT program plan.

40.3(3) Technician utilization plan. The pharmacy technician utilization plan shall specifically identify the individual certified pharmacy technicians authorized to participate in the TCT program and shall identify in detail the types of work that the certified pharmacy technicians may perform and check. The pharmacy shall include participation in the TCT program in the defined duties of any certified pharmacy technician authorized to participate in the TCT program, and if the certified pharmacy technician is authorized to check the work of other certified pharmacy technicians, that function shall be clearly identified in the checking technician’s duties.

40.3(4) Certified pharmacy technician participation. All of the following shall apply to a certified pharmacy technician authorized to participate in a TCT program.

a. National certification. The certified pharmacy technician’s national certification shall be current and in good standing.

b. Iowa registration. The certified pharmacy technician’s registration with the board shall be current, in good standing, and not currently subject to disciplinary charges or sanctions.

c. Prior experience. The checking technician shall be working at the pharmacy full- or part-time and shall have met the experience requirement for a checking technician as specified in policies and procedures and in the TCT program plan.

d. Training. The certified pharmacy technician shall complete site-specific training in the TCT program and the functions to be performed by the certified pharmacy technician as part of the TCT program.

e. Specialized training for checking technician. A certified pharmacy technician who is a checking technician shall receive specialized and advanced training as provided in policies and procedures, including training in the prevention, identification, and classification of medication errors. The training program for a checking technician shall be didactic in nature and shall include successful completion of a competency test.

40.3(5) Responsible individuals. The pharmacist in charge may designate one pharmacist to be responsible for meeting TCT program training and validation requirements and may designate one or more pharmacists to supervise the activities of certified pharmacy technicians authorized to participate in the TCT program. A pharmacist supervising TCT program activities shall provide program plan evaluation information to the responsible pharmacist or the pharmacist in charge for collection and analysis. Each individual involved in the TCT program shall be responsible for the activities performed by that individual and for ensuring that those activities adhere to the TCT program policies and
procedures and comply with board rules. The pharmacist in charge shall be ultimately responsible for TCT program activities and for development and implementation of TCT program policies and procedures.

40.3(6) Policies and procedures. Parameters for supervising the activities of certified pharmacy technicians participating in the TCT program, including but not limited to specialized and advanced training for checking technicians, shall be specified in policies and procedures regarding the utilization of pharmacy technicians. Policies and procedures shall provide for continuous evaluation of certified pharmacy technicians authorized to participate in the TCT program, shall identify benchmarks and sentinel events, shall define an excessive overall error rate, shall address certified pharmacy technician retraining procedures, and shall address pharmacy staffing.

40.3(7) Staffing. Pharmacy staffing shall be adequate to ensure consistent and safe implementation of the TCT program and to optimize pharmacist patient care services.

40.3(8) Pharmacist review. Except in an emergency, when the pharmacy is closed, or when the prescriber is directly supervising and overseeing the administration of the drug to the patient, a pharmacist shall review all orders against a medication profile as required by rule 657—8.21(155A). A pharmacist shall be on site and available to certified pharmacy technicians during any period that TCT functions are being performed.

40.3(9) Additional drug check prior to administration. The drug distribution system shall be structured so that at least one additional check of dispensed drugs, following dispensing and checking by a checking technician, is completed by a licensed health care professional in the facility prior to administration of the drug to the patient. A licensed health care professional or certified medication aide shall administer the drug to the patient. The TCT program plan shall identify the individuals authorized to administer the drug to the patient. The identification of these individuals may consist of a description of the classification of the authorized individuals, such as “registered nurse,” “licensed practical nurse,” or “certified medication aide,” or the identification may specifically identify the authorized individuals by name and title. Alternatively, the identification may reference an existing facility policy or procedure that identifies or specifies the individuals authorized to administer a drug to a patient.

40.3(10) Program evaluation. Implementation of a TCT program shall result in the redirection of the pharmacist from distributive tasks to cognitive and patient care activities. As part of an ongoing program review and evaluation as provided in subrule 40.4(5), the pharmacist in charge or designee shall document the specific cognitive and patient care activities, and a summary of the approximate amount of time pharmacists spend on those activities, as a result of implementation of the TCT program. Program review and evaluation records shall be available for inspection and copying by the board or its representatives and any other authorized agencies for two years following the date of the record.

[ARC 9783B, IAB 10/5/11, effective 11/9/11]

657—40.4(155A) TCT program requirements. A TCT program shall be conducted in compliance with the following requirements.

40.4(1) Training of checking technician. No certified pharmacy technician shall be designated or authorized by the pharmacist in charge or responsible pharmacist to perform, nor shall a certified pharmacy technician perform, the function of checking the work of another certified pharmacy technician without having received and satisfactorily completed the specialized and advanced training provided for in the pharmacy’s policies and procedures. The specialized training shall include the prevention, identification, and classification of medication errors. Training requirements shall include provisions for retraining of a checking technician who fails to maintain the level of competence necessary for the performance of authorized duties as demonstrated by the technician’s failure to satisfactorily meet ongoing evaluation and competency audits.

40.4(2) Authorized checking functions. A certified pharmacy technician authorized by the pharmacist in charge or responsible pharmacist to check the work of another certified pharmacy technician may check activities relating to the filling of floor stock, unit dose distribution systems, proprietary bag and vial systems or manufactured premix intravenous products, and AMDS components for hospital and long-term care facility patients. Medication orders shall have previously been reviewed
by a licensed pharmacist against the patient’s medication profile, and the prepared drugs shall be checked by at least one additional licensed health care professional in the facility at the time the drugs are administered to a patient. The checking function performed by the checking technician shall be limited to those types of drugs identified in the written TCT program plan, and the TCT program plan shall specifically describe the method for verifying cassette or drug bin fills.

40.4(3) Certified pharmacy technician evaluation. The responsible pharmacist shall conduct continuous monitoring and evaluation of each certified pharmacy technician authorized to participate in the TCT program in order to ensure the continued competency of the certified pharmacy technicians and the safety of patients. As a component of the pharmacy’s continuous quality improvement program and except as otherwise specifically provided by these rules, errors shall be identified and records maintained as provided in rule 657—8.26(155A).

a. Periodic review and pharmacist check. Evaluation shall include periodic review and checking by the pharmacist of work checked by the checking technician and identification and documentation of all errors not identified and corrected by the checking technician.

b. Review of errors identified by pharmacist or checking technician. The responsible pharmacist shall review with all certified pharmacy technicians involved any errors identified during the evaluation and shall discuss procedures to ensure the errors are not repeated.

c. Review of errors identified following release by checking technician. The responsible pharmacist shall receive, evaluate, and review with all certified pharmacy technicians involved any errors identified by a health care professional, a certified medication aide, a patient, or any other individual following release of a drug by the checking technician.

40.4(4) Records. The pharmacist in charge shall maintain in the pharmacy department a record for each certified pharmacy technician authorized by the pharmacist in charge or responsible pharmacist to participate in the TCT program. The record shall be available for inspection and copying by the board or its representatives and any other authorized agencies for two years beyond the term of the certified pharmacy technician’s employment. The record shall include:

a. The name of the certified pharmacy technician.

b. The date on which the certified pharmacy technician completed the site-specific training for participation in the TCT program.

c. The date on which the certified pharmacy technician was authorized to participate in the TCT program and the specific TCT program functions and tasks the certified pharmacy technician is authorized to perform.

d. If the certified pharmacy technician is authorized to check the work of other certified pharmacy technicians, the date on which the checking technician completed the specialized and advanced training as provided in policies and procedures.

e. The dates and results of all competency evaluations.

f. The dates of and reasons for any suspension or revocation of the certified pharmacy technician’s TCT program authorization, identification of corrective action or retraining completed, and the date of the subsequent reinstatement of the certified pharmacy technician’s TCT program authorization.

g. The dates of and reasons for any disciplinary action taken against the certified pharmacy technician in connection with the certified pharmacy technician’s performance of duties relating to the TCT program.

40.4(5) TCT program evaluation. The pharmacist in charge shall maintain in the pharmacy department program evaluation records that demonstrate the redirection of pharmacist activities from distributive tasks to cognitive and patient care activities. The approximate amount of time each pharmacist spent on specific distributive tasks and on specific cognitive and patient care activities prior to implementation of the TCT program shall be documented in the program evaluation records and shall be maintained for the duration of the TCT program. Program evaluation records shall identify the specific cognitive and patient care activities and a summary of the approximate amount of time pharmacists spend on those activities as a result of implementation of the TCT program. TCT program evaluation records shall be updated at least semiannually and shall be available for inspection and
copying by the board or its representatives and any other authorized agencies for two years following the date of the record.

[ARC 9783B, IAB 10/5/11, effective 11/9/11]

These rules are intended to implement Iowa Code sections 147.107, 155A.6A, and 155A.33.

[Filed ARC 9783B (Notice ARC 9557B, IAB 6/15/11), IAB 10/5/11, effective 11/9/11]
A. General requirements.
   (1) A New Mexico licensed pharmacy located in New Mexico may employ one or more
   certified pharmacy technicians for the purpose of data input in remote practice sites provided that all security
   requirements are met.
   (2) All pharmacy technicians employed to work at a remote data entry practice site must be
   registered as a certified pharmacy technician with the board and have a minimum of one year experience performing
   data entry functions as a certified pharmacy tech.
   (3) All remote pharmacy technician data entry sites will operate under a New Mexico
   licensed pharmacy located in New Mexico under the authority of its pharmacist-in-charge.
   (4) No drug inventory shall be kept at any remote pharmacy technician data entry site and no
   dispensing shall take place from a remote pharmacy technician data entry site.
   (5) All remote pharmacy technician data entry sites will have a procedure for identifying the
   pharmacy technician and the pharmacist responsible for each aspect of the prescription preparations.
   (6) All remote pharmacy technician data entry sites will have quality monitoring and
   improvement programs in place.

B. Personnel.
   (1) The pharmacist-in-charge shall:
       (a) provide a written policy and procedure document outlining the operation and
           security of each remote pharmacy technician data entry sites location; the document shall be available at each
           practice site;
       (b) keep a continuously updated list of all remote pharmacy technician data entry
           sites to include address, phone number and hours of operation for each site; the record shall be retained as part of the
           records of the licensed pharmacy;
       (c) is responsible for ensuring that the New Mexico licensed pharmacy and each
           remote data entry pharmacy technician has entered into a written agreement outlining all conditions and policies
           governing the operation of the remote site;
       (d) ensure that all computer equipment used at the remote site is in good working
           order, provides data protection and complies with all security and HIPAA requirements.
   (2) Data entry pharmacy technician shall:
       (a) be a certified pharmacy technician registered with the board and reside in New
           Mexico;
       (b) have a minimum of one year experience performing data entry functions as a
           certified pharmacy technician;
       (c) be trained in the use of all equipment necessary for secure operation of the
           remote site.

C. Operations.
   (1) If the remote pharmacy technician data entry sites is located within a home there must be
       a designated area in which all of the pharmacy technicians work will be performed.
   (2) All computer equipment used at the remote pharmacy technician data entry sites must be
       able to establish a secure connection which the site is operating. Remote equipment must be configured so that
       patient information is not stored at the remote site electronically or in printed form.
   (3) Computer equipment may only be used for remote pharmacy technician data entry. No
       other use of equipment will be allowed.
   (4) Computer equipment must be locked or shut down whenever the pharmacy technician is
       absent.
   (5) All remote pharmacy technician data entry sites are subject to unannounced inspection by
       representatives of the New Mexico board of pharmacy during established hours of operation.

D. Security.
   (1) Remote pharmacy technician data entry sites shall have adequate security to maintain
       patient confidentiality.
   (2) Must utilize equipment that prevents unauthorized storage or transfer of patient
       information.
   (3) If the remote site is in a home, the equipment must be located in a designated area where
       patient information cannot be viewed by anyone other than the remote pharmacy technician.

HISTORY OF 16.19.6 NMAC:
Pre-NMAC History: The material in this part was derived from that previously filed with the State Records Center and Archives:
BOP 69-2, Rules and Regulations of the State Board of Pharmacy, 6-13-69.
BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act, 7-31-72.
Regulation No. 6, Pharmacies, 2-7-80.
Regulation No. 6, Pharmacies, 10-23-85.
Regulation No. 6, Pharmacies, 2-2-87.
Regulation No. 6, Pharmacies, 7-27-90.

History of Repealed Material:
BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act - Repealed, 10-29-85.
16 NMAC 19.6, Pharmacists - Pharmacies, filed 08-27-99, Repealed effective 03-30-02.
#A16. STLCoP and UMKC College of Pharmacy

- STLCoP Site Listing
- STLCoP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing
- Future Approval of STLCoP & UMKC Preceptor/Pharmacy Site Lists
#A17. Applications for Intern Training Special Site/Non-Pharmacist Preceptor

- Ascension
- Faith Community Health Clinic
- Missouri Pharmacy Association
- Moberly Regional Medical Center Pharmacy
- Pharmacie de la Tour
- Rusk Rehabilitation Center
- US Food and Drug Administration, Silver Spring, MD
- Washington University
#A18. Election of Officers
#A19. **Legal Contract Approval**

- Curtis Thompson
- Newman, Comley and Ruth
Thursday, July 13, 2017
10:30 A.M. – 1st case
BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI

MISSOURI BOARD OF PHARMACY, )
) Petitioner,
) )
) v. ) Case No. 2016-002902
) )
Gerald J. Cipponeri, R.PH., )
) Respondent.
)

NOTICE OF FELONY DISCIPLINARY HEARING

PLEASE TAKE NOTICE that the Missouri Board of Pharmacy, is in receipt of a Felony Conviction Complaint filed with the Board May 3, 2017, as a result of your guilty plea or being found guilty on or about August 17, 2016, to one count of felony Possession of a Controlled Substance by Fraud or Forgery in the United States District Court, Eastern District of Missouri. No answer or responsive pleading is required to the complaint. No Board rules exist regarding discovery in this matter.

NOW THEREFORE, the Missouri Board of Pharmacy shall, pursuant to Section 338.065.1, RSMo, hold a hearing for the discipline of your pharmacist license. A Felony Disciplinary Hearing has been scheduled for Thursday, July 13, 2016, at 10:30 a.m., first case on the docket, at the Courtyard Columbia, 3301 Lemone Industrial Blvd., Columbia, Missouri. Please be advised your failure to appear at the hearing at the above-noted time and place will result in the hearing being held in your absence. All parties should prepare a minimum of ten (10) copies of all exhibits to be presented during the hearing.

All parties have the right to be represented by legal counsel and to a full, fair and open hearing as provided for in Chapter 536, RSMo, and Section 621.110, RSMo.

Dated this _ day of June, 2017

By: KIMBERLY A. GRINSTON
   EXECUTIVE DIRECTOR
   MISSOURI BOARD OF PHARMACY
CERTIFICATE OF SERVICE

I hereby certify that I have mailed a copy of the Notice of Felony Disciplinary Hearing by certified mail this ___ day of June, 2017 to:

Gerald Cipponeri, R.Ph.
P.O. Box 394
905 Lake
Sullivan, MO 63080

I further certify that a copy of the Notice of Felony Disciplinary Hearing was mailed by first-class mail to Midwest Litigation Services, 3432 West Truman Blvd, Suite 207, Jefferson City, MO 65109, and to Cotton Walker, Cotton Walker & Associates, 1739 East Elm, Suite 101, Jefferson City, MO 65101.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR
Date Produced: 06/05/2017

WALZ GROUP:

The following is the delivery information for Certified Mail™/RRE item number 9314 8699 0430 0034 5445 67. Our records indicate that this item was delivered on 06/02/2017 at 02:45 p.m. in SULLIVAN, MO 63080. The scanned image of the recipient information is provided below.

Signature of Recipient:

[Handwritten signature]

Address of Recipient:

905 Lake Rd

Thank you for selecting the Postal Service for your mailing needs. If you require additional assistance, please contact your local post office or Postal Service representative.

Sincerely,
United States Postal Service

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Information in this section provided by Walz Group, LLC.

Recipient Information:
Gerald Cipponeri, R.Ph
905 LAKE RD
P.O. Box 394
SULLIVAN, MO 63080

Reference Number: Dis. Hearing 2016-002902
BEFORE THE MISSOURI
BOARD OF PHARMACY
STATE OF MISSOURI

MISSOURI STATE BOARD
OF PHARMACY

Petitioner,

v.

GERALD CIPPONERI,

Respondent.

Case No. 2014-002902

FELONY CONVICTION COMPLAINT

COMES NOW Petitioner, Missouri State Board of Pharmacy, by and through its Counsel, Cotton Walker, and hereby requests that a disciplinary hearing be scheduled before the Board pursuant to §338.065 RSMo\(^1\) for the following reasons:

1. The Missouri State Board of Pharmacy ("Board") is an agency of the State of Missouri created and established pursuant to § 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. Respondent, Gerald Cipponeri, is licensed by the Board as a pharmacist, license number 042806.

3. Respondent’s license was current and active at all times material herein.

4. On August 17, 2016, Respondent pled guilty in the United States District Court, Eastern District of Missouri, to the crime of Possession of a Controlled Substance by Fraud or Forgery in violation of Title 21, United States Code, §843(a)(3), in case number 4:15-cr-00529-CEJ.

\(^1\) All statutory references are to the Revised Statutes of Missouri as supplemented unless otherwise noted.
5. In his written plea of guilty, Respondent admitted he knowingly or intentionally acquired or obtained possession of a controlled substance, by misrepresentation, fraud, forgery, deception, or subterfuge.

6. On November 15, 2016, a Judgment in that criminal case was entered and sentence was imposed by United States District Judge, Carol E. Jackson.

7. A certified copy of the Guilty Plea Agreement and Judgment in a Criminal Case with terms and sentence information is attached as Exhibit A and is incorporated by reference as if fully set out herein.

8. Information in the Guilty Plea Agreement confirmed Respondent knowingly and intentionally obtained prescription drugs, which included controlled substances, by taking them from his employer by fraud, where he was employed as a pharmacist.

9. Title 21, United States Code, §843(a)(3), provides:

(a) UNLAWFUL ACTS. It shall be unlawful for any person knowingly or intentionally --

(3) To acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;


11. The Board has cause to discipline Cipponeri’s license pursuant to §338.065.1, RSMo Supp. 2013, which states:

At such time as the final trial proceedings are concluded whereby a licensee or registrant, or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit, or license, has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, in a felony prosecution pursuant to the laws of the state of Missouri, the laws of any other state, territory, or the laws of the United States of America for any offense reasonably related to the qualifications, functions or duties of a licensee, permittee, or registrant pursuant to this chapter or any felony offense,
an essential element of which is fraud, dishonesty or an act of violence, or for any felony offense involving moral turpitude, whether or not sentence is imposed, the board of pharmacy may hold a disciplinary hearing to singly or in combination censure or place the licensee, permittee, or registrant named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, registration or permit.

WHEREFORE, based on the foregoing, Petitioner prays the Missouri Board of Pharmacy conduct a hearing consistent with §338.065.1, RSMo, and impose such discipline as the Board deems appropriate and just under the circumstances.

Respectfully submitted,

S. Cotton Walker

Cotton Walker
Attorney at Law
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Cotton.Walker@CottonWalkerLaw.com
ATTORNEY FOR MISSOURI
STATE BOARD OF PHARMACY
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

GERALD J. CIPPONERI,

Defendant

GUILTY PLEA AGREEMENT

Come now the parties and hereby agree, as follows:

1. PARTIES:

   The parties are the defendant GERALD J. CIPPONERI, represented by defense counsel Richard H. Sindel, and the United States of America (hereinafter "United States" or "Government"), represented by the Office of the United States Attorney for the Eastern District of Missouri. This agreement does not, and is not intended to, bind any governmental office or agency other than the United States Attorney for the Eastern District of Missouri. The Court is neither a party to nor bound by this agreement.

2. GUILTY PLEA:

   Pursuant to Rule 11(c)(1)(A), Federal Rules of Criminal Procedure, in exchange for the defendant's voluntary plea of guilty to Counts One through Five of the charge, the Government agrees that no further federal prosecution will be brought in this District relative to the defendant's receipt and possession of child pornography between July 1, 2011, and May 22, 2014, of which the Government is aware at this time. In addition, the parties agree that the U. S. Sentencing Guidelines Total Offense Level analysis agreed to by the parties herein is the result of negotiation.
and led, in part, to the guilty plea. Furthermore, the parties recommend to the Court that a four-level downward variance be granted, which the parties believe will adequately reflect the seriousness of the offense and provide just punishment for the offense. The parties agree that other than requesting the four-level downward variance, neither party shall request a sentence above or below the U.S. Sentencing Guidelines range (combination of Total Offense Level and Criminal History Category) ultimately determined by the Court pursuant to any chapter of the Guidelines, Title 18, United States Code, Section 3553, or any other provision or rule of law not addressed herein.

The defendant also agrees, pursuant to the guilty pleas, to forfeit to the United States all items seized by law enforcement, including his Hitachi Digital hard drive, Western Digital hard drive, Seagate Backup Plus Digital hard drive, and Seagate Barracuda XT Digital hard drive (hereafter, collectively, “the defendant’s hard drives”).

The defendant also agrees to voluntarily surrender his Missouri pharmacy license and submit an Affidavit of Voluntary Surrender of Pharmacist License to the Missouri Board of Pharmacy.

The parties understand that the District Court is neither a party to nor bound by the Guidelines recommendations agreed to in this document.

3. **ELEMENTS:**

As to Counts One through Four, the defendant admits to knowingly violating Title 18, United States Code, Section 2252A(a)(5)(B), and admits there is a factual basis for the plea and further fully understands that the elements of the crime of Possession of Child Pornography, which he admits to knowingly committing are: (1) defendant knowingly possessed material that contained images of child pornography, (2) which were visual depictions where the production of
such visual depictions involved the use of a minor engaging in sexually explicit conduct and such visual depictions were of a minor engaging in sexually explicit conduct, and (3) those images are contained on material that has been transported in interstate commerce and were themselves transported in interstate commerce.

As to Count Five, the defendant admits to knowingly violating Title 21, United States Code, Section 843(a)(3), and admits there is a factual basis for the plea and further fully understands that the elements of the crime of Possession of a Controlled Substance by Fraud or Forgery, which he admits to knowingly committing are: defendant knowingly or intentionally acquired or obtained possession of a controlled substance, by misrepresentation, fraud, forgery, deception, or subterfuge.

4. FACTS:

The parties agree that the facts in this case are as follows and that the government would prove these facts beyond a reasonable doubt if the case were to go to trial. These facts may be considered as relevant conduct pursuant to Section 1B1.3:

On October 18, 2013, during an authorized undercover operation, Detective Adam Kavanaugh of the St. Louis County Police Department identified an IP address where a computer in the State of Missouri was offering to participate in the distribution of child pornography. Det. Kavanaugh directly connected and successfully browsed the publicly available files of the computer at the IP address and was able to identify a specific video file known to contain child pornography. The file name associated with the file is "(pthc) webcam — 5yr & 1ly daughters show yours (1)[1]." Additionally, other connections were made with a computer at the same IP address and additional files of child pornography were downloaded from a computer using that IP address.
Fidelity Communications was subpoenaed to identify to whom the IP address was assigned on the dates and times in question. Fidelity Communications' records indicated that during those dates and times, the IP address was assigned to S Cipponeri at 725 Falcon Dr. Apt A, Sullivan, MO 63080, in the Eastern District of Missouri.

On May 22, 2014, law enforcement officers from the St. Louis County Police Department and St. Charles County Sheriff's Department executed a search warrant at the defendant's residence. The defendant was at his home when the search warrant was executed. After clearing the house for other occupants, Det. Coyne sat down at the kitchen table to speak with the defendant. After having it explained to him that he was not under arrest and could leave at any time, the defendant agreed to speak with the law enforcement officers. During the interview, the defendant admitted that he lived at the residence but denied downloading child pornography. The defendant claimed that if he ever came across it he would delete it right away. He also stated he would batch download pornography and would not know what he had until he looked at it. If it looked underage, the defendant claimed he deleted it. Defendant also admitted that he had a HP tower computer with several hard drives and six or seven external hard drives (law enforcement later determined he had 27.5 terabytes of storage on his computer).

Despite defendant's claims, however, the defendant had moved some of the files containing child pornography from his Ares download folder to other hard drives and devices. Forensic analysis also found that the defendant used Ares search terms such as "pteh" (pre-teen hard core) and "hussyfan," and other search terms commonly used to search for child pornography. The defendant also admitted to having downloaded one of the child pornography videos just the night before, but claimed he deleted it as soon as he figured out what it was. However, he had watched it first, as he recognized the video when investigators played it for him.
During the execution of the search warrant, several items were seized including two cell phones, defendant’s HP computer tower, nine external hard drives, a USB power port, three USB cords, and an Ipad. The hard drives and other media were forensically examined and found to contain fifty-nine (59) files of suspected child pornography (19 image files, 40 videos) on seven (7) different devices. Over thirty (30) terabytes of data was analyzed. The child pornography files depicted minor children under and around the age of twelve years old in displays of sexually explicit contact and graphic nudity. Both the computer and external hard drives were produced outside the state of Missouri and therefore traveled in interstate commerce.

Det. Kavanaugh located child pornography on the defendant’s hard drives including, but not limited to, the following:

1) “(pitch) vicky.mpg” — a video file of a minor female engaged in sexual intercourse with an adult male;

2) “niña de caliente.mpg” — a video file of a minor female performing oral sex on an adult male;

3) “pthc new 2011 12yr vagina wide open.avi” — a video file of a minor female in lascivious display of her genitals;

4) “9yr jenny suck little dog cock.mpg” — a video file of a minor female in lascivious display of her genitals while being bound with rope and in which minor female also performs oral sex on an adult male;

5) “09 years old vicky mummy anal (4)(2).mpg” — a video file of a minor female receiving anal sex from an adult male;

6) “(~pthc center~)(opva)(2012) latina violada 7 aos y feliz(2).avi” — a video file of a prepubescent minor female engaged in sexual intercourse with an adult male;
7) “!!!!! hot hot hot !!!!! - 13y bondage.avi” — a video file of a minor female engaged in sexual intercourse with an adult male; and
8) “(kingpass) - marissa.avi” — a video file of a minor female engaged in anal sex and performing oral sex on an adult male.

Thus, and as defendant now admits, between July 1, 2011, and May 22, 2014, defendant knowingly possessed the aforementioned child pornography images on his hard drives and those images were transported in interstate commerce. Defendant also admits that the hard drives traveled in interstate and foreign commerce.

The internet is a computer communications network using interstate and foreign lines to transmit data streams, including data streams used to store, transfer and receive graphic files. The internet is a means and facility of interstate and foreign commerce.

At all times relevant, the defendant worked as a pharmacist at a pharmacy in Sullivan, MO. He began working at the pharmacy in October 2010 on a part-time basis. He was later hired full-time and was given full access to controlled medication and keys to the facility.

During the execution of the search warrant at the defendant’s house, officers located and seized drugs, drug paraphernalia, and numerous prescription pills, including Carisoprodol 350MG. The defendant admitted to officers that the marijuana found in the office area was his and that he used it recreationally after work. On the night stand in the bedroom was a clear bag of prescription pills that contained nineteen (19) pills that included ten (10) Clonazepam tablets (a Schedule IV controlled substance), four (4) Carisoprodol tablets, one (1) tablet containing Zolpidem (a Schedule IV controlled substance), and a fragment of a tablet that contained Alprazolam (a Schedule IV controlled substance).

The pharmacy at which the defendant worked conducted a controlled substance audit to see
if any medications were unaccounted for. The audit period was from November 9, 2013 through June 11, 2014 (the defendant began working there in October 2010), and showed there was an unaccounted for shortage of Alprazolam 2MG, Lorazepam 2MG, and Carisoprodol 350 MG.

During the execution of the search warrant, the defendant admitted that he did not have prescriptions for the drugs seized from his home. The defendant had taken them without proper authority from the pharmacy at which he worked. Consequently, the defendant knowingly and intentionally obtained those prescription drugs, which included controlled substances, by misrepresentation, fraud, forgery, deception, and subterfuge.

5. **STATUTORY PENALTIES:**

As to Counts One through Four, the defendant fully understands that the maximum possible penalty provided by law for the crime of Possession of Child Pornography to which the defendant is pleading guilty is imprisonment of not more than ten years, and a fine of not more than $250,000. The Court may also impose a period of supervised release of not more than life and not less than five years.

As to Count Five, the defendant fully understands that the maximum possible penalty provided by law for the crime of Possession of a Controlled Substance by Fraud or Forgery to which the defendant is pleading guilty is imprisonment of not more than four years, and a fine of not more than $250,000. The Court may also impose a period of supervised release of not more than three years.

6. **U.S. SENTENCING GUIDELINES: 2014 MANUAL:**

The defendant understands that this offense is affected by the U. S. Sentencing Guidelines and the actual sentencing range is determined by both the Total Offense Level and the Criminal History Category.
The parties agree that the following are the U.S. Sentencing Guidelines Total Offense Level provisions that apply to Counts One through Four:

a. **Chapter 2 Offense Conduct:**

(1) **Base Offense Level — Possession of Child Pornography (Counts One through Four):** The parties agree that the base offense level is eighteen (18) as found in Section 2G2.2(a)(1).

(2) **Specific Offense Characteristics:** The parties agree that the following Specific Offense Characteristics apply:

   (a) two (2) levels should be added pursuant to Section 2G2.2(b)(2), because “the material involved a prepubescent minor or a minor who had not attained the age of 12 years,”

   (b) four (4) levels should be added pursuant to Section 2G2.2(b)(4), because “the offense involved material that portrays sadistic or masochistic conduct or other depictions of violence,”

   (c) two (2) levels should be added pursuant to Section 2G2.2(b)(6), because “the offense involved the use of a computer or an interactive computer service for the possession, transmission, receipt, or distribution of the material,” and

   (d) five (5) levels should be added pursuant to Section 2G2.2(b)(7), because “the offense involved 600 or more images.”

The parties agree that the following are the U.S. Sentencing Guidelines Total Offense Level provisions that apply to Count Five:
(3) **Base Offense Level — Possession of a Controlled Substance by Fraud or Forgery (Count Five):** The parties agree that the base offense level is eight (8) as found in Section 2D2.2.

(Pursuant to Section 3D1.4, because the offense level of Count Five is nine (9) or more levels less serious than the Group with the highest offense level, Count Five will not increase the applicable offense level.)

b. **Chapter 3 Adjustments:**

(1) **Acceptance of Responsibility:** The parties agree that three levels should be deducted pursuant to Section 3E1.1(a) and (b), because the defendant has clearly demonstrated acceptance of responsibility and timely notified the government of the defendant's intention to plead guilty. The parties agree that the defendant's eligibility for this deduction is based upon information presently known. If subsequent to the taking of the guilty plea the government receives new evidence of statements or conduct by the defendant that it believes are inconsistent with defendant's eligibility for this deduction, the government may assert that the defendant should not receive all or part of the deduction pursuant to Section 3E1.1.

(2) **Other Adjustments:** The parties recommend that the following adjustments, other than acceptance of responsibility, apply: none.

c. **Estimated Total Offense Level:** The parties estimate that the Total Offense Level is twenty eight (28). Furthermore, the parties recommend to the Court that a four-level downward variance be granted, which the parties believe will adequately reflect the seriousness of the offense and provide just punishment for the offense.
d. **Criminal History:** The determination of the defendant's Criminal History Category shall be left to the Court. Either party may challenge, before and at sentencing, the finding of the Presentence Report as to the defendant's criminal history and the applicable category. The defendant's criminal history is known to the defendant and is available in the Pretrial Services Report.

e. **Effect of Parties' U.S. Sentencing Guidelines Analysis:** The parties agree that the Court is not bound by the Guidelines analysis agreed to herein. The parties may not have foreseen all applicable Guidelines. The Court may, in its discretion, apply or not apply any Guideline despite the agreement herein and the parties shall not be permitted to withdraw from the plea agreement.

7. **WAIVER OF APPEAL AND POST-CONVICTION RIGHTS:**

a. **Appeal:** The defendant has been fully apprised by defense counsel of the defendant's rights concerning appeal and fully understands the right to appeal the sentence under Title 18, United States Code, Section 3742.

   (1) **Non-Sentencing Issues:** The parties waive all rights to appeal all non-jurisdictional, non-sentencing issues, including, but not limited to, any issues relating to pretrial motions, discovery and the guilty plea.

   (2) **Sentencing Issues:** In the event the Court accepts the plea, accepts the U.S. Sentencing Guidelines Total Offense Level agreed to herein, and, after determining a Sentencing Guidelines range, sentences the defendant within or below that range, then, as part of this agreement, the defendant hereby waives all rights to appeal all sentencing issues other than Criminal History. Similarly, the Government hereby waives all rights to appeal all sentencing issues other than Criminal History, provided the Court accepts the plea, the agreed Total Offense
b. **Habeas Corpus:** The defendant agrees to waive all rights to contest the conviction or sentence in any post-conviction proceeding, including one pursuant to Title 28, United States Code, Section 2255, except for claims of prosecutorial misconduct or ineffective assistance of counsel.

c. **Right to Records:** The defendant waives all rights, whether asserted directly or by a representative, to request from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including any records that may be sought under the Freedom of Information Act, Title 5, United States Code, Section 522, or the Privacy Act, Title 5, United States Code, Section 552(a).

8. **OTHER:**

a. **Disclosures Required by the United States Probation Office:**

The defendant agrees to truthfully complete and sign forms as required by the United States Probation Office prior to sentencing and consents to the release of these forms and any supporting documentation by the United States Probation Office to the government.

b. **Civil or Administrative Actions not Barred; Effect on Other Governmental Agencies:**

Nothing contained herein limits the rights and authority of the United States to take any civil, tax, immigration/deportation or administrative action against the defendant.

c. **Supervised Release:**

Pursuant to any supervised release term, the Court will impose standard conditions upon the defendant and may impose special conditions related to the crime defendant committed. Some of these special conditions may include that defendant not possess a computer or internet
access, that defendant not have contact with minors without the authorization of the Probation Officer, that defendant participate in sexual offender counseling and that defendant not maintain a post office box. In addition, as a condition of supervised release, defendant shall initially register with the state sex offender registration in Missouri, and shall also register with the state sex offender registration agency in any state where defendant resides, is employed, works, or is a student, as directed by the Probation Officer. The defendant shall comply with all requirements of federal and state sex offender registration laws.

These and any other special conditions imposed by the Court will be restrictions with which defendant will be required to adhere. Violation of the conditions of supervised release resulting in revocation may require the defendant to serve a term of imprisonment equal to the length of the term of supervised release, but not greater than the term set forth in Title 18, United States Code, Section 3583(c)(3), without credit for the time served after release. The defendant understands that parole has been abolished. If, while on supervised release for this case, the defendant commits a new criminal offense under Chapters 109A, 110 or 117, or Title 18, United States Code, Sections 1201 or 1591, for which imprisonment for a term longer than one year can be imposed, the defendant shall be sentenced on the supervised release revocation to not less than five years and up to life imprisonment for this offense.

d. **Mandatory Special Assessment:** Pursuant to Title 18, United States Code, Section 3013, the Court is required to impose a mandatory special assessment of $100 per count for a total of $500, which the defendant agrees to pay at the time of sentencing. Money paid by the defendant toward any restitution or fine imposed by the Court shall be first used to pay any unpaid mandatory special assessment.
Pursuant to Title 18, United States Code, Section 3014, for offenses occurring on or after May 29, 2015, and before October 1, 2019, the Court is required to impose an assessment of $5,000 on any non-indigent defendant convicted of an offense under—

(1) Chapter 77 (relating to peonage, slavery, and trafficking in persons, including, but not limited to, 18 U.S.C. § 1591 (Sex trafficking of children or by force, fraud, or coercion));

(2) Chapter 109A (relating to sexual abuse);

(3) Chapter 110 (relating to sexual exploitation and other abuse of children, including, but not limited to, 18 U.S.C. §2251(a) (production of child pornography) and 18 U.S.C. § 2252A (transportation, distribution, receipt, possession, or access with intent to view child pornography));

(4) Chapter 117 (relating to transportation for illegal sexual activity and related crimes, including, but not limited to, 18 U.S.C. § 2422(b) (enticement of a child) and 18 U.S.C. § 2423 (transportation of minors)); or

(5) Section 274 of the Immigration and Nationality Act (8 U.S.C. 1324) (relating to human smuggling), unless the person induced, assisted, abetted or aided only an individual who at the time of such action was the alien’s spouse, parent, son, or daughter (and no other individual) to enter the United States in violation of the law.


e. Possibility of Detention: The defendant shall be subject to immediate detention pursuant to the provisions of Title 18, United States Code, Section 3143.
f. **Fines, Restitution, and Costs of Incarceration and Supervision:**

The Court may impose a fine, restitution (in addition to any penalty authorized by law), costs of incarceration and costs of supervision. The defendant agrees that any fine or restitution imposed by the Court will be due and payable immediately. Pursuant to Title 18, United States Code, Sections 3663A and 2259, an order of restitution is mandatory for all crimes listed in Sections 3663A(c) and 2259. Regardless of the Count of conviction, the amount of mandatory restitution imposed shall include all amounts allowed by Sections 3663A(b) and 2259 and the amount of loss agreed to by the parties, including all relevant conduct loss. The defendant agrees to provide full restitution to all victims of all charges in the indictment without regard to the count or counts to which the defendant has agreed to plead guilty.

g. **Forfeiture:**

The defendant agrees to forfeit all of the defendant's interest in all items seized by law-enforcement officials during the course of their investigation, including, but not limited to, Hitachi Digital hard drive, Western Digital hard drive, Seagate Backup Plus Digital hard drive, and the Seagate Barracuda XT Digital hard drive. The defendant admits that all United States currency, weapons, property and assets seized by law enforcement officials during their investigation constitute the proceeds of the defendant's illegal activity, were commingled with illegal proceeds or were used to facilitate the illegal activity. The defendant agrees to execute any documents and take all steps needed to transfer title or ownership of said items to the government and to rebut the claims of nominees and/or alleged third party owners. The defendant further agrees that said items may be disposed of by law enforcement officials in any manner. The defendant hereby knowingly and intelligently waives any rights the defendant may have (a) for notice of the forfeiture to be given in the charging document, (b) for a jury or the Court determine
what of defendant's property is subject to forfeiture, (c) for the Court to explain the forfeiture at the
defendant's change of plea hearing, and (d) for the forfeiture to be made part of the oral
pronouncement of sentence and included in the judgment.

9. ACKNOWLEDGMENT AND WAIVER OF THE DEFENDANT'S RIGHTS:

In pleading guilty, the defendant acknowledges, fully understands and hereby waives his
rights, including but not limited to: the right to plead not guilty to the charges; the right to be tried
by a jury in a public and speedy trial; the right to file pretrial motions, including motions to suppress
evidence; the right at such trial to a presumption of innocence; the right to require the government
to prove the entire case against the defendant beyond a reasonable doubt; the right not to testify; the
right not to present any evidence; the right to be protected from compelled self-incrimination; the
right at trial to confront and cross-examine adverse witnesses; the right to testify and present
evidence and the right to compel the attendance of witnesses. The defendant further understands
that by this guilty plea, the defendant expressly-waives all the rights set forth in this paragraph.

The defendant fully understands that the defendant has the right to be represented by
counsel, and if necessary, to have the Court appoint counsel at trial and at every other stage of the
proceeding. The defendant's counsel has explained these rights and the consequences of the
waiver of these rights. The defendant fully understands that, as a result of the guilty plea, no trial
will, in fact, occur and that the only action remaining to be taken in this case is the imposition of the
sentence.

Defendant understands that by pleading guilty, defendant will be subject to federal and state
sex offender registration requirements, and that those requirements may apply for life. The
defendant understands that defendant must keep said registrations current, shall notify the state sex
offender registration agency or agencies of any changes to defendant's name, place of residence,
employment, or student status, or other relevant information. Defendant shall comply with requirements to periodically verify in person said sex offender registration information. Defendant understands that defendant will be subject to possible federal and state penalties for failure to comply with any such sex offender registration requirements. If defendant resides in Missouri following release from prison, defendant will be subject to the registration requirements of Missouri state law. Defendant further understands that, under 18 U.S.C. § 4042(c), notice will be provided to certain law enforcement agencies upon release from confinement following conviction. Defense counsel has advised the defendant of the possible sex offender registration consequences resulting from the plea.

If the defendant is not a U.S. citizen, the guilty plea could impact defendant's immigration status or result in deportation. In particular, if any crime to which defendant is pleading guilty is an "aggravated felony" as defined by Title 8, United States Code, Section 1101(a)(43), removal or deportation is presumed mandatory. Defense counsel has advised the defendant of the possible immigration consequences, including deportation, resulting from the plea.

The defendant is fully satisfied with the representation received from defense counsel. The defendant has reviewed the government's evidence and discussed the government's case and all possible defenses and defense witnesses with defense counsel. Defense counsel has completely and satisfactorily explored all areas which the defendant has requested relative to the government's case and any defenses.

10. **VOLUNTARY NATURE OF THE GUILTY PLEA AND PLEA AGREEMENT:**

This document constitutes the entire agreement between the defendant and the government, and no other promises or inducements have been made, directly or indirectly, by any agent of the government, including any Department of Justice attorney, concerning any plea to be entered in this
case. In addition, the defendant states that no person has, directly or indirectly, threatened or coerced the defendant to do or refrain from doing anything in connection with any aspect of this case, including entering a plea of guilty.

The defendant acknowledges having voluntarily entered into both the plea agreement and the guilty plea. The defendant further acknowledges that this guilty plea is made of the defendant's own free will and that the defendant is, in fact, guilty.

11. **CONSEQUENCES OF POST-PLEA MISCONDUCT:**

After pleading guilty and before sentencing, if defendant commits any crimes, other than minor traffic offenses, violates any conditions of release that results in revocation, violates any term of this guilty-plea agreement, intentionally provides misleading, incomplete or untruthful information to the U.S. Probation Office or fails to appear for sentencing, the United States, at its option, may be released from its obligations under this agreement. The Government may also, in its discretion, proceed with this agreement and may advocate for any sentencing position supported by the facts, including but not limited to obstruction of justice and denial of acceptance of responsibility.

12. **NO RIGHT TO WITHDRAW GUILTY PLEA:**

Pursuant to Rule 11(c) and (d), Federal Rules of Criminal Procedure; the defendant understands that there will be no right to withdraw the plea entered under this agreement, except where the Court rejects those portions of the plea agreement which deal with charges the government agrees to dismiss or not to bring.

*SCHLAGER WICK, #501043DC*

Assistant United States Attorney

17
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St. Louis, Missouri 63102

8/15/2016
Date

GERALD Z. CIPONERI
Defendant

8/17/18
Date

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