AMENDED Meeting Notice
Missouri Board of Pharmacy
January 10-11, 2018 (Wednesday-Thursday)

The Broadway Columbia
1111 E Broadway
Columbia, Missouri

***DUE TO A WINTER WEATHER ADVISORY FOR THE NORTHERN PART OF THE STATE AND POTENTIAL INCLEMENT WEATHER, THE CLOSED SESSION BOARD MEETING ON JANUARY 11TH WILL BE HELD VIA CONFERENCE CALL***

Notice is hereby given that the Missouri Board of Pharmacy will be meeting on January 10 – 11, 2017. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Broadway Columbia, 1111 E. Broadway, Columbia, Missouri at 8:00 a.m. on January 10-11, 2017.

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

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

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

TENTATIVE AGENDA

JANUARY 10-11, 2018

The Broadway Columbia
1111 E. Broadway
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***DUE TO A WINTER WEATHER ADVISORY AND POTENTIAL INCLEMENT WEATHER, THE CLOSED SESSION BOARD MEETING ON JANUARY 11TH WILL BE HELD VIA CONFERENCE CALL***

January 10-11, 2018

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

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

#A2. Roll Call

***The Board will go immediately into closed session and will reconvene in open session at approximately 8:30 a.m. on January 10, 2018***

#A3. Agenda Additions/Corrections

#A4. 2020 Rule Review

(Public comment will be limited to three (3) minutes per participant)

- Rule Review Calendar
- 20 CSR 2220-5.010 (Drug Distributor Advisory Committee)
- 20 CSR 2220-5.020 (Drug Distributor Licensing Requirements)
- 20 CSR 2220-5.025 (Termination of Business as a Drug Distributor)
- 20 CSR 2220-5.030 (Definitions and Standards for Drug Wholesale and Pharmacy Distributors)
- 20 CSR 2220-5.040 (Drug Distributor Inspection Exemptions)
- 20 CSR 2220-5.050 (Out-of-State Distributor License/Registration Requirements)
- 20 CSR 2220-5.060 (Controlled Substance Reporting)
- 20 CSR 2220-5.070 (Standards of Operation for Medical Gas Distributors)

#A5. Draft Rule Amendments

(Draft revisions of the following rules are currently under review)

- 20 CSR 2220-2.010 Pharmacy Standards of Operation
State language on humidity

- 20 CSR 2220-2.012 Pharmacy Supervision
  - State definitions of pharmacy supervision
- 20 CSR 2220-2.090 Pharmacist-In-Charge

#A6. Rules Under Initial Review
(The Board will discuss potential changes for the following rules; Suggestions will be incorporated into a draft rule for discussion at a future meeting)

- 20 CSR 2220-2.110 (PRN Refills)
- 20 CSR 2220-2.120 (Transfer of Rx Information for Refill)
- 20 CSR 2220-2.130 (Drug Repackaging)
- 20 CSR 2220-2.190 (Patient Counseling)
  - Staff Research

#A7. FY 2017 Annual Report
- Draft Report

#A8. 2018 Practice Guide Revision
- Draft 2018 Practice Guide

#A9. Red Tape Reduction Report/Rule Amendments

- 1.010
- 1.020
- 2.015
- 2.016
- 2.050
- 2.060
- 2.080
- 2.110
- 2.120
- 2.150
- 2.170
- 2.175
- 2.180
- 2.300
- 2.600
- 2.675
- 2.800
- 2.950
- 3.011
- 5.010
#A10. Board Member Meetings Report
- Nuclear Sub-Committee
- DMH/NPA Naloxone Training

#A11. General Administration Report
- Staff/Office Update
- Financial Report
- 2018 Renewal Fee Decrease
- Rule Update
- Patient Safety Conference Survey
- Springfield Board Compliance Conference Survey
- NABP Annual Meeting (May 5-8 2018 – Denver, Colorado)

#A12. Inspection/Investigation Report
- Inspection/Investigation Updates

#A13. Hospital Advisory Committee Update

#A14. Implementation of SB 501/Rx Cares for Missouri Program

#A15. Review of 20 CSR 2220-2.950 (Automated Filling Systems)


#A17. Fiscal Year 2018-2019 Strategic Plan

#A18. Compounding For Office Use/Repackaging
- November 6, 2017 Correspondence to the Board

#A19. NABP Telepharmacy Request for Comments
- NABP Letter to State Boards

#A20. STLCOP and UMKC College of Pharmacy
- STLCOP Site Listing
- STLCOP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing

#A21. Applications for Intern Training Special Site/Non-Pharmacist Preceptor
- DST Pharmacy Solutions, Inc.
- CVS/Pharmacy Management
- Schnucks Corporate Offices/Specialty Pharmacy Division
- Genesis HealthCare System-Information Technology
#A22. Board Disciplinary Report (For Informational Purposes)

#A23. Board Licensing Statistics (For Informational Purposes)

#A24A. Approval of Open Session Minutes
   • July 2017
   • August 2017

#A25. 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.

#A25. Adjournment
January 10-11, 2018

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• 1.010  2.180  6.030
• 1.020  2.300  6.055
• 2.015  2.600  7.010
• 2.016  2.675  7.025
• 2.050  2.800  7.027
• 2.060  2.950  7.030
• 2.080  3.011  7.040
• 2.110  5.010  7.050
• 2.120  5.020  7.070
• 2.150  5.025  7.080
• 2.170  5.050
• 2.175  5.060

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- 20 CSR 2220-5.070 (Standards of Operation for Medical Gas Distributors)
Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 5—Drug Distributor

20 CSR 2220-5.010 Drug Distributor Advisory Committee

PURPOSE: This rule establishes operating guidelines for the drug distributor advisory committee.

(1) As authorized in section 338.140.4., RSMo, an advisory committee, composed of five (5) members, one (1) of whom shall be a representative of pharmacy, but who shall not be a member of the pharmacy board, three (3) of whom shall be representatives of wholesale drug distributors, as defined in section 338.330, RSMo, and one (1) of whom shall be a representative of drug manufacturers, shall be appointed by the State Board of Pharmacy.

(2) Appointments to the advisory committee shall be made by the president of the board.
   (A) Except for the initial committee appointments, each appointment shall be for a term of five (5) years. Beginning with the first committee appointments, the terms will be staggered so that one (1) term will expire each year after that.
   (B) No appointment shall become effective until approved by the board. Each candidate shall meet with the board prior to any decision by the board to confirm. This meeting will be held in order for the board to review the candidate’s credentials and to familiarize him/her with board personnel and advisory committee responsibilities.
   (C) Terms of new committee members shall commence on July 1, unless the appointment is to fill an unexpired term.

(3) The advisory committee shall organize by the election of a chairman and vice-chairman who shall hold their offices for one (1) year and until their successors shall have been elected and qualified. A majority of the committee shall constitute a quorum for the transaction of business.

(4) The advisory committee shall review and make any recommendations to the board on the merit of all rules dealing with pharmacy distributors, wholesale drug distributors and drug manufacturers which are proposed by the board.
   (A) The advisory committee shall maintain minutes of all meetings held.
   (B) Any recommendations made by the advisory committee concerning proposed regulations shall be noted and explained in the minutes which will be provided to the board at an open session meeting of the board. The advisory committee may provide other documentation, reports or correspondence to the board when necessary.
(C) Any official recommendations to be made from the committee to the board must be initiated by a motion that receives a majority vote in favor by the committee. This motion and vote shall be recorded in the minutes.

(D) The board will review any recommendations made by the advisory committee and will provide a response to the committee if any action is taken or modifications are made to a proposed regulation. In addition, the board shall note in the Missouri Register the dates and a summary of any recommendations made by the advisory committee on a proposed rule and report any responses that are made to those recommendations from the board.

(5) Committee members shall be reimbursed or all reasonable and necessary expenses for attending committee meetings. However, only expenses incurred within Missouri will routinely be reimbursed. No request for the compensation of expenses provided in this rule shall be processed for payment unless sufficient funds are available for that purpose within the appropriation of the State Board of Pharmacy.


PURPOSE: This rule defines terms and requirements for the lawful licensure of drug distributors.

(1) A “wholesale drug distributor” is defined in section 338.330(3), RSMo. No wholesale drug distributor with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also include, but not be limited to, notification from the board by mail or electronic transmission.

(A) A wholesale drug distributor is further defined as anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(B) Licensure and/or registration as a wholesale drug distributor is not required for activities described below—

1. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, transfer, or trade a drug for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. The amount sold, purchased, transferred, or traded shall not exceed five percent (5%) of the pharmacy’s total gross prescription sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total drug purchases;

2. The sale, purchase, or trade of blood and blood components intended for transfusion and any other exemptions as provided for in Chapter 338, RSMo;

3. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, or trade a drug by a Missouri licensed pharmacy that does not exceed five percent (5%) of the pharmacy’s total gross sales. For purposes of this section, total gross sales shall be calculated based on the pharmacy’s total annual prescription drug sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total drug purchases;

4. The sale, purchase, transfer, or trade of a drug or offer to sell, purchase, transfer, or trade a drug among hospitals or by a hospital to a healthcare entity under the same common control or ownership as the hospital. “Common control or ownership” means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership, stock, voting rights, contract, or otherwise. For purposes of this rule, a “hospital” shall be limited to a hospital as defined by Chapter 197, RSMo, or a hospital operated by the state;
5. The storage or distribution of drugs by a local, state, or federal facility that are received from the Strategic National Stockpile or the state stockpile for the purpose of providing those drugs in an emergency situation as authorized by a state or federal agency;

6. The sale, purchase, transfer, or trade of a prescription drug to alleviate a temporary shortage of a prescription drug that is in limited supply or unavailable due to delays in or interruption of supply. Drugs sold, purchased, transferred, or traded pursuant to this section shall only be sold, purchased, transferred, or traded directly from an importer or manufacturer authorized by or registered with the United States Food and Drug Administration (FDA) to import or manufacture the drug that is unavailable or in short supply. In addition, sales, purchases, transfers, or trades shall be limited to the period of shortage and to the drug that is unavailable or in limited supply. Documentation of FDA authorization or registration shall be maintained in the licensee’s or recipient’s records; and

7. The sale, purchase, transfer, or trade of a drug between a Missouri licensed pharmacy and a non-resident pharmacy that is located in and licensed by another state or United States territory. The total amount of drug sold, purchased, transferred, or traded by the Missouri-licensed pharmacy pursuant to this subsection shall not exceed five percent (5%) of the pharmacy’s total annual prescription drug sales. Missouri pharmacies receiving drugs pursuant to this section from a non-resident pharmacy shall maintain the following records for two (2) years from the date of sale, purchase, transfer, or trade:

   A. Proof the non-resident pharmacy holds a current pharmacy license in the state or territory from which the drug is shipped or distributed; and

   B. An invoice record which documents the name and address of the non-resident pharmacy, the date of sale, purchase, transfer, or trade, and the name, strength, and quantity of the drug received. The pharmacies shall also comply with all applicable controlled substance requirements.

   (C) Wholesale drug distributors shall inform the board of their current FAX number, any change in FAX number, and/or the fact that the wholesale drug distributor does not have a working FAX. In the event a wholesale drug distributor notifies the board that the wholesale drug distributor does not have a working FAX, notification from the board will be made to the wholesale drug distributor by first class mail. For the purposes of this rule, such notification by mail shall be considered effective three (3) days after mailing and shall have the same effect as notification by FAX.

   (D) Failure to receive notification from the board shall not be a defense to violations of section (1) of this rule when the wholesale drug distributor has failed to comply with the requirements of subsection (1)(C) of this rule.

(2) All licenses for the operation of a drug distributor shall expire on the date specified by the director of the Division of Professional Registration by appropriate rule.
(3) Drug distributor licenses shall be issued on the application of the owners. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along with the appropriate fees before any license is issued or renewed. Information required on the application shall include:

(A) The name, full business address, electronic facsimile transmission number (FAX), and telephone number of the licensee;

(B) All trade or business names used by the licensee;

(C) The address, telephone number, and the name of the manager in charge for each facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(D) The type of ownership or operation;

(E) The name(s) of the owner, operator, or both, of the licensed entity, including:

1. If a person, the name of the person;
2. If a partnership, the name of each partner and the name of the partnership;
3. If a corporation, the name of the corporate president, vice president, secretary, treasurer, chief executive officer, board of directors, and senior vice presidents or their equivalents, the corporate name(s), and the name of the state of incorporation; and
4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(F) The name of the manager-in-charge who meets the requirements as set forth in 20 CSR 2220-5.030(2); a complete notarized manager-in-charge affidavit of the license application; and a history of employment/occupations and offices held during the past seven years; and

(G) An application for a wholesale or pharmacy drug distributor license will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(5) When a drug distributor changes ownership, the original license becomes void on the effective date of the change of ownership. Before any new business entity resulting from that change opens a facility as a drug distributor, it must obtain a new license from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license shall be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(A) A change of ownership of a drug distributor facility owned by a sole proprietor is deemed to have occurred when—
1. The business is sold and the sale becomes final;
2. The proprietor enters into a partnership with another individual or business entity; or
3. The proprietor dies; provided, however, that the proprietor’s estate may continue to
   operate the drug distributor facility for a period of no more than one (1) year and only so
   long as appropriate fees are paid.

(B) If a corporation owns a drug distributor facility, it is not necessary to obtain a new
license if the owners of the stock change. If a limited liability partnership or a limited
liability company owns a drug distributor company, it is not necessary to obtain a new
license if the partners or members of the company change, as long as the partnership or
company is not dissolved by that change. It is necessary to file written notice with the Board
of Pharmacy within thirty (30) days after a change occurs of twenty-five percent (25%) or
more in the ownership of corporation stock, or in partners in a limited liability partnership,
or in members of the limited liability company. This notification must be in writing and
certified. However, when a corporation, limited liability partnership, or limited liability
company begins ownership of a drug distributor company or ceases ownership of a drug
distributor company, a new license must be obtained regardless of the relationship between
the previous and subsequent owners.

(6) If an individual or business entity operating a drug distributor facility changes the
location of the facility either within the existing facility (structure) or to a new facility
(structure), the facility shall not open for business at the new location until the board, its
duly authorized agent, or the Food and Drug Administration has inspected the premises of
the new location and approved it
and the facility has been in compliance with all state and federal drug laws pertaining to
drug distribution. Upon this approval and receipt of a change of location fee, the board shall
issue a license authorizing operation of a facility at the new location and the license shall
bear the same number as the previous license. However, the license remains valid if the
facility address changes, but not the location, and an amended license will be issued without
charge under these circumstances.

(7) Separate licenses shall be required for each drug distribution site owned or operated by a
drug distributor as defined in section 338.330, RSMo.

(8) The Board of Pharmacy may grant a temporary license to a wholesale or pharmacy drug
distributor to allow for the conduct of business within the state until a determination by the
board is made on the issuance of a permanent license.
   (A) Temporary licenses shall remain valid until a time the board shall find that the
   applicant meets or fails to meet the requirements for regular licensure or one (1) year,
   whichever is less.
   1. The board will consider, at a minimum, the following factors in reviewing the
      qualifications of persons who apply or renew as a drug distributor:
A. Any convictions of the applicant under any federal, state, or local laws relating to
drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
B. 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;
C. The applicant’s past experience in the manufacture or distribution of prescription
drugs, including controlled substances;
D. The applicant furnishing false or fraudulent material in any application made in
connection with drug manufacturing or distribution;
E. Suspension, revocation, or probation by federal, state, or local government of any
license or registration currently or previously held by the applicant for the manufacture or
distribution of any drugs, including controlled substances;
F. Compliance with licensing requirements under previously granted licenses, if any;
and
G. Requirements to maintain or make available, or both, to the board or the federal,
state, or local law enforcement officials those records required under this section are
followed.
2. If an applicant for a license in any way fails to provide information as requested by
the board or does not cooperate with requests and inquiries made by the board or provides
false or misleading information to the board and the temporary license expires or is denied,
all fees paid by the applicant shall be forfeited.
3. During the period of time that a temporary license is in effect, the applicant may
conduct business in this state as a drug distributor as long as all state and federal laws
governing drug distribution are followed and no action that results in professional
misconduct as outlined in section 338.055, RSMo is documented.
4. If it is determined by the board that a permanent license is to be denied to an
applicant, a denial notification letter shall be sent to the applicant. The temporary license
will be considered invalid ten (10) days after notification is sent to the applicant by certified
mail.
(B) A license must be posted in a conspicuous place in the facility to which it is issued.
(9) Each licensed corporate wholesale distributor located outside of this state that distributes
drugs in this state shall designate a registered agent in this state for service of process. Any
licensed corporate wholesale distributor that does not designate a registered agent shall be
deemed to have designated the secretary of state of this state to be its true and lawful
attorney, upon who may be served all legal process in any action or proceeding against any
licensed corporate wholesale distributor growing out of or arising from such distribution.
Service of process shall be accomplished as authorized by law.

20 CSR 2220-5.025 Termination of Business as a Drug Distributor

PURPOSE: This establishes guidelines for the termination of business as a drug distributor.

(1) A licensed drug distributor who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the license and shall include the following information:

(A) The name, address, license number and effective date of closure;
(B) The name, address and license number of the entity to which any of the stock/inventory will be transferred; and
(C) The name and address of the location to which records, required to be maintained by law, have been transferred;

1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board;
2. Any records that are transferred to a licensed drug distributor or pharmacy must be maintained in accordance with record requirements as set forth in 4 CSR 220-5.030.

(2) The licensee terminating business may transfer all drugs and records in accordance with the following:

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the drug distributor terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer;
(B) A drug distributor terminating business shall not transfer misbranded, outdated or adulterated drugs, except for purposes of proper disposal; and
(C) Upon the actual termination of business, the license of the drug distributor shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a drug distributor.

(4) The termination date is the date on which the drug distributor licensee ceases to do business as a distributor as defined in section 338.330(1), (2) or (3), RSMo in the state of Missouri.

PURPOSE: This rule provides standards for the proper storage, maintenance, labeling and
distribution of drugs by drug wholesale and pharmacy distributors, and further defines
methods of inspections and quality assurance used by the Board of Pharmacy to ensure the
public’s safety in these areas. For purposes of this rule, the term drug distributor will be
used to define all entities that are licensed under section 338.330, RSMo and are subject to
this rule.

(1) Drug distributors must maintain standards of practice that will ensure that only drugs of
appropriate quality will be distributed to practitioners for further compounding and
dispensing to the public. These standards shall be subject to periodic reviews through the
board’s inspection process.

(A) This process will include on-site inspections for drug distributors who are located in
this state and may include border states or by requesting information on licensure and
inspections conducted by other states or the federal government through the board office.

(B) For purposes of this rule, the term drug distributor, when used, defines anyone en-
gaged in any activity as defined in section 338.330, RSMo.

(2) No drug distributor license will be issued unless the facility is under the direct
supervision of a manager-in-charge.

(A) The board shall consider the same factors in reviewing the qualifications of someone
who is appointed as a manager-in-charge as those outlined in 20 CSR 2220-5.020(8)(A)1.

(B) A person must also have appropriate education, experience, or both, before as-suming
the duties of manager-in-charge. Appropriate education for purposes of this section is
defined as education in the areas of work environment, standards of operation and
knowledge of laws concerning drug distributor compliance and requirements.

1. Minimum requirements for education/experience may be attained separately or in
combination to total two (2) years.

2. Experience within a drug wholesale or pharmacy distributor facility or in any
education endeavor beyond a certificate of graduation from an accredited high school or its
equivalent may be utilized in meeting these minimum requirements.

(C) Any individual that is considered a manager or supervisor within a facility but is not
the manager-in-charge of the facility must meet the minimum education/experience
requirements as set forth in this rule for a total of one (1) year.

(D) The licensee shall require all other persons employed in any prescription drug
wholesale distribution activity to have education, training and experience, or any
combination, sufficient for that person to perform the assigned functions in a manner as to
provide assurance that the drug product quality, safety and security at all times will be
maintained as required by law.
(E) Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge. The manager-in-charge must be actively involved and aware of the actual daily operations of the drug distributor operation. The manager-in-charge must be physically present at the drug distributor operation during normal business hours, except for time periods when absent due to illness, scheduled vacation or other authorized absence; and be aware of, and knowledgeable about, all polices and procedures pertaining to the operations of the drug distributor operation. When the person who is manager-in-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or termination of the manager-in-charge and by notarized affidavit give the name of the new manager-in-charge.

(3) Minimum standards of practice for drug distributors shall include the following:

(A) The facility must be of a suitable size and construction to facilitate cleaning, maintenance and proper operations;

(B) The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the United States Pharmacopeia (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs;

(C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.

1. All aisles and walkways must be free and clear of debris, dirt or filth.

2. Dust shall be kept at low levels through adequate ventilation, cleaning procedures, or both.

3. All shelves and storage areas shall be kept free of debris, dirt, dust and filth.

4. Full cases of drug products shall be raised above floor level and placed on a pallet or similar device.

5. Upon receipt of legend drugs, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

6. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

7. Drugs stored in a facility or being processed for distribution must be physically separated at all times from articles, supplies or other drugs that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances or accumulated waste/garbage. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other
prescription drugs until they are either destroyed or returned to the supplier. If a drug is received or further distributed, either directly or through a secondary broker (paper) transaction, that is wholly or in part found to be counterfeit, a report which includes the name of the drug, quantity and lot number(s) must be forwarded to the Board of Pharmacy within seven (7) days of gaining knowledge of the transaction. Any recall of a product that is initiated by the Food and Drug Administration (FDA) or by a vendor licensed with the state of Missouri shall not be subject to the reporting requirement.

8. Flammable articles must be stored separately and away from drug products held for later wholesale distribution.

9. Drugs which may be held for later distribution that are labeled for veterinary use must be stored separately from those drugs that are to be distributed for human use.

10. Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or vermin of any kind. Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in the drug storage areas.

11. Appropriate sewage disposal and a hot and cold water supply must be available.

12. The outside perimeter of the premises shall be well-lighted.

13. All facilities shall be equipped with an alarm system to detect entry after hours.

14. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

(D) The drug distributor license issued to the facility must be displayed in a public area;

(E) Adequate refrigeration must be available to ensure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both;

(F) The labeling of drug products held for wholesale distribution must conform to requirements as set forth by the manufacturer, FDA, the USP and section 338.059.2, RSMo;

(G) If the conditions under which a prescription drug has been returned cast doubt on the drug’s safety, identity, strength, quality or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug’s safety, identity, strength, quality or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling, as a result of storage or shipping;
(H) Drugs held for wholesale distribution must be stored in a secure area where only
authorized personnel have access to them. Sufficient locking mechanisms must be in place
and a list of personnel who possess keys or passes which allow them to have independent
access to any part of a facility which stores drugs held for later distribution or where any
controlled substances are stored must be maintained. Records on all past employees who
have had access to drug storage or processing areas must be maintained for a period of three
(3) years;

(I) Wholesale drug and pharmacy distributors shall establish and maintain inventories and
records of all transactions regarding the receipt and distribution or other disposition of
prescription drugs. These records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or
transferor and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs;

(J) Inventories and records shall be made available for inspection and photocopying by
authorized federal, state or local law enforcement agency officials for a period of three (3)
years following disposition of the drugs;

(K) Records described in this section that are kept at the inspection site or that can be
immediately retrieved by computer or other electronic means shall be readily available for
authorized inspection during the retention period. Records kept at a central location apart
from the inspection site and not electronically retrievable shall be made available for
inspection within two (2) working days of a request by the board or its representatives;

(L) Record requirements as described in this rule shall be followed for appropriate
accountability and disposition for all outdated, damaged, deteriorated, misbranded or
adulterated prescription drugs;

(M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to
written policies and procedures, which shall be followed for the receipt, security, storage,
inventory and distribution of prescription drugs, including policies and procedures for
identifying, recording and reporting losses or thefts and for correcting all errors and
inaccuracies in inventories. Drug distributors shall include in their written policies and
procedures the following:

1. A procedure where the oldest approved stock of a prescription drug product is
distributed first. The procedure may permit deviation from this requirement if the deviation
is temporary and appropriate;

2. A procedure to be followed for handling recalls and withdrawals of prescription
drugs. This procedure shall be adequate to deal with recalls and withdrawals due to any—
A. Action initiated at the request of the FDA or other federal, state, or local law
enforcement or other government agency, including the Board of Pharmacy;

B. Voluntary action by the manufacturer to remove defective or potentially defective
drugs from the market; or
C. Action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

3. A procedure to ensure that drug distributors prepare for, protect against and handle any crisis that affects the security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency;

4. A procedure for reporting counterfeit or suspected counterfeit drugs or devices or counterfeiting or suspected counterfeiting activities to the board;

5. A procedure for the mandatory reporting to the board and any other appropriate federal or state agency of all shortages of prescription drugs and devices where it is known or suspected that diversion or theft is occurring;

6. A procedure for investigating discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband in the inventory and reporting such discrepancies within seven (7) business days to the board and any other appropriate federal or state agency shall be maintained by each drug distributor;

7. A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) and device(s) to the board within the seven (7) business days; and

8. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs.

(N) Drug distributors will be responsible for security procedures for the delivery of drugs from the wholesale facility to the destination site of all drug shipments; and

(O) No drug distributor license shall be issued to any location, regardless of zoning, that is a residence or that shares an address and/or physical space with a business not related to the distribution of prescription drugs or drug-related devices, or not licensed and regulated by the state of Missouri.

(4) In addition to standards listed in this rule for drug distributors, drug repackagers must observe federal standards for—

(A) Packaging;

(B) Record keeping;

(C) Expiration dating;

(D) Plant facilities;

(E) Equipment;

(F) Personnel;

(G) Production and control procedures;

(H) Containers;

(I) Testing; and

(J) Federal registration requirements.
(5) Agents or employees of licensed or registered drug distributors may have legend drugs in their custody if they are acting in the usual course of business or employment and their names and addresses and the addresses of all sites where drugs are stored have been provided to the board.

(A) Storage and transport of drugs by agents or employees of drug distributors must be maintained in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration or adulteration.

(B) Drug distributors shall report to the board any agents or employees that are registered pursuant to this section of this rule for any convictions for violations of state or federal drug laws.

(6) Drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(7) Drug distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Parts 207, 210 and 211 of the Federal Food, Drug and Cosmetic Act.

(8) The executive director of the board, at his/her discretion, may grant exemptions to compliance with portions of section (3) of this rule when such exemptions are not contrary to federal drug distributor laws and the exemption is limited to a specific request. Any exemption requests by a licensed drug distributor must be submitted in writing. Any exemptions that are granted as outlined in this section will be provided in writing.

(9) As used in section 338.330(3), RSMo, the term “drug related device” shall be defined as an article that is not considered a prescription drug under federal law, but which meets the definition of a device as provided in 21 U.S.C. 321(h) and 21 U.S.C. 360j(e).


20 CSR 2220-5.040 Drug Distributor Inspection Exemptions

PURPOSE: This rule defines requirements for Board of Pharmacy inspection exemption of wholesale drug and pharmacy distributors.

(1) Inspections of drug distribution facilities shall be conducted by the board in accordance with the provisions as outlined in section 338.360, RSMo. Any drug distributor facility which has been inspected by the Food and Drug Administration (FDA) over a period of less than two (2) years and can demonstrate that all inspections resulted in a satisfactory rating shall be exempt from further inspection by the board until and upon the time that any inspection of the premises of the facility results in a less than satisfactory rating or the last full inspection by the FDA is two (2) years old or greater.

(A) For purposes of this rule, the results of federal inspections that are deemed to be less than satisfactory shall include, but not be limited to, any documentation as to deficiencies in any drug distribution, repackaging, labeling, quality control or environmental policies or procedures, or both. Deficiencies may be defined as any statement which is a part of a compliance report recorded by federal inspection with or without sanctions, penalties, fines or discipline imposed.

1. For purposes of further definition, an inspection that is conducted by the FDA that is used for exemption purposes must be a full inspection of all operations and procedures of the facility. Abbreviated inspectional options as defined in federal policy guidelines may not be considered to fulfill the exemption requirements as provided in section 338.360, RSMo and this rule.

2. Any drug distribution facility which has been granted an exemption from inspection must notify the board at any time of an inspection conducted by the FDA or the Drug Enforcement Administration that results in less than a satisfactory rating as defined in subsection (1)(A) of this rule.


20 CSR 2220-5.050 Out-of-State Distributor License/Registration Requirements

PURPOSE: This rule establishes guidelines for license/registration procedures for out-of-state drug distributors.

(1) Out-of-state wholesale drug distributors or out-of-state pharmacy distributors may be licensed, as required by sections 338.210—338.370, RSMo, by reciprocity if they—

(A) Possess a valid license in good standing in the state or foreign jurisdiction in which they are located pursuant to legal standards comparable to those which must be met by a distributor of this state as prerequisites for obtaining a license under the laws of this state; and

(B) Are located in a state or foreign jurisdiction which extends reciprocal treatment under its own laws to a wholesale distributor of this state.

(2) Out-of-state wholesale drug and pharmacy distributors shall not ship, mail or deliver prescription drugs into Missouri without first obtaining a license from the Missouri Board of Pharmacy.

(A) In order for an out-of-state wholesale drug or pharmacy distributor to maintain a license, it must comply with each of the following:

1. Maintain in good standing a license from the state or foreign jurisdiction in which the nonresident distributor is located provided that a license is issued by that state or foreign jurisdiction;

2. Submit an application as provided by the board for licensure in compliance with sections 338.333 and 338.337, RSMo and with 4 CSR 220-5.020;

3. Pay all appropriate fees;

4. Submit a copy of the state or foreign jurisdiction license or its equivalent from the state or foreign jurisdiction in which the distributor is located provided that a license is issued by that state or foreign jurisdiction;

5. Submit a copy of the state or foreign jurisdiction and federal controlled substance registrations from the state or foreign jurisdiction in which they are located, if controlled substances are to be shipped into Missouri; and

6. Submit copies, when requested by the board, of any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state or foreign jurisdiction in which it is located concerning the operation of an out-of-state drug or pharmacy distributor for review of compliance with state, federal or foreign jurisdiction drug laws.

(B) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state or foreign jurisdiction that licenses and regulates out-of-state drug or pharmacy distributors for the purpose of investigating complaints against distributors located in Missouri or the sharing of information and investigative reports, as long as the other state or foreign jurisdiction will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.
An exemption to licensure is allowed when an out-of-state wholesale drug distributor supplies a drug to another drug distributor licensed in this state in an emergency situation. The amount of the distribution allowed must be confined to the emergency situation and the total amount of distribution for emergency situations must not exceed one percent (1%) of the total annual gross sales of the unlicensed distribution site.

Registration in lieu of licensure may be sought by an out-of-state drug distributor when the following provisions exist:

(A) The out-of-state drug distributor is a drug manufacturer;

(B) The manufacturing facility is used for both the production (manufacture) and distribution of legend drugs;

(C) The site has been inspected with a satisfactory rating by the Food and Drug Administration within the last two (2) years. Inspections of these facilities must comply with all standards and requirements as outlined in 4 CSR 220-5.040;

(D) The state in which the manufacturing facility is located issues a license and the license is current and in good standing; and

(E) The out-of-state distributor who qualifies for registration must complete an application as provided by the board and submit it along with a filing fee of ten dollars ($10).

1. The board shall provide, on an annual basis, a registration renewal form to all registered out-of-state distributors.

2. In order for a registration to remain in good standing and in effect, the renewal must be returned to the Division of Professional Registration by an expiration date that is specified by the director of the division by appropriate rule.

3. In order for a registration to be renewed, it must comply with all the provisions for registering as a drug distributor facility as outlined in section 338.337, RSMo and this rule.

4. Each renewal application must be submitted along with a filing fee of ten dollars ($10).


PURPOSE: This rule defines requirements for reporting the distribution of controlled substances from drug and pharmacy distributors to persons and facilities that are registered with the Federal Drug Enforcement Administration.

(1) Wholesale drug and pharmacy distributors that distribute Schedule II products and Schedule III narcotics Automation of Reports and Consolidated Orders (ARCOS products) shall provide a listing of those products distributed within the state to the board on a quarterly basis when requested to do so by the board. In addition, wholesale drug and pharmacy distributors that distribute controlled substances within the state shall provide up to a twenty-four (24) month retrospective listing of all controlled substances (Schedule II through Schedule IV) distributed within the state or to a specific location to the board when requested to do so by the board. The board shall submit the request thirty (30) days in advance of the information requested. Reports must be submitted to the board either on hard copy in typewritten form or by electronic media. If electronic media is used in providing the reports, it shall be provided in one (1) of the following formats.

(A) If an electronic tape is used, it shall be an IBM 9-track, labeled or nonlabeled, 1600 or 6250 bits per inch (bpi);

(B) If a diskette is used, it shall be either a Macintosh 400K or 800K; MS-DOS 5 1/4" 360K or 1.2 meg; MS-DOS 3 1/2" 720K or 1.44 meg; or an IBM 8" diskette; or

(C) If a cartridge is used, it shall be a 1/2" tape, 3480 Compatible.


20 CSR 2220-5.070 Standards of Operation for Medical Gas Distributors

PURPOSE: This rule establishes standards of operation for medical gas distributors. This proposed rule has been reviewed by the Drug Distributor Advisory Committee as required by section 338.140.4, RSMo.

(1) Medical gases are defined as compressed gases and liquid gases that a distributor or manufacturer has labeled for medical use in compliance with federal law.

(2) Medical gas distributor is defined as an entity which is licensed by the board as a drug distributor and is involved in the distribution of medical gases and related medical devices pursuant to a medical gas order to medical gas suppliers and other entities that are registered, licensed or permitted to use, administer or distribute medical gases.

(3) Medical gas distributors that are not involved in the storage or transfer of any other federal legend drugs and only store, transfer or transfill medical grade gas products other than nitrous oxide are exempt from the following regulation sections: 20 CSR 2220-5.030(3)(B); (3)(C)4., 9., 12., and 13.; (3)(E); and (3)(M)4. Medical gas distributors that store, transfer or transfill nitrous oxide are exempt from 20 CSR 2220-5.030(3)(B); (3)(C)4. and 9.; (3)(E) and (3)(M)4. All other drug distributor requirements contained within the board’s regulations shall be considered applicable to medical gas distributors.

(4) A medical gas distributor that is involved in the manufacture/transfilling of medical gases must register with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with the drug listing requirements of the federal act. In addition, all current good manufacturing practice requirements as set forth in 21 CFR 210 through 211 must be complied with.


#A5. Draft Rule Amendments

(Draft revisions of the following rules are currently under review)

- 20 CSR 2220-2.010 Pharmacy Standards of Operation
  - State language on humidity
- 20 CSR 2220-2.012 Pharmacy Supervision
  - State definitions of pharmacy supervision
- 20 CSR 2220-2.090 Pharmacist-In-Charge
20 CSR 2220-2.010 Pharmacy Standards of Operation

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

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

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

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

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

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

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

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

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

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

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

(C) Generally recognized reference(s) or other peer-reviewed resource(s) that include the following items/topics:
   1. Pharmacology of drugs;
   2. Dosages and clinical effects of drugs; and
   3. Patient information and counseling.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(D) Date of action;

(E) Reason for action; and

(F) Any additional information required by law.

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

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

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

1. Injectable dosage forms of sodium chloride and water;

2. Irrigation dosage forms of sodium chloride and water;

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

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

5. Vaccines; and

6. Tuberculin test material.

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

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

2. Indications for use of the drugs possessed;

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

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

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

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

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

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

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

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

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

Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

Phar 6.01 Licenses; application. Requirements and procedures for applying for a pharmacy license are specified in s. 450.06, Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by contacting the board office. A license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy license. A pharmacy may not operate unless a pharmacy license has been granted. Board action shall be taken within 60 business days of receipt of a completed pharmacy application, as provided in s. SPS 4.03.

Phar 6.02 Licenses; change of location or ownership. (1) A pharmacy license authorizes a pharmacy to operate only at the location designated on the license. Licenses may not be transferred to another location.

1m) A hospital which has a pharmacy area providing outpatient pharmacy services which is physically separate from, and not contiguous to the area from which inpatient pharmacy services are provided, shall have a pharmacy license for the outpatient pharmacy in addition to a license for the inpatient pharmacy.

(2) Any change in pharmacy ownership shall be reported to the board office and the pharmacy license of the former owner returned. A pharmacy license shall be granted to the new pharmacy owner before the pharmacy may operate.

Phar 6.03 Changes in managing pharmacist. The pharmacy owner shall report to the board any change of managing pharmacist within 5 days following the change.

Phar 6.04 Floor design. (1) PROFESSIONAL SERVICE AREA. The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk pharmaceuticals. If the pharmacy is open at any time solely as a non-prescription or sundry outlet, without a pharmacist present, the professional service area shall be secured as specified in sub. (3). A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service area plan varies from the requirement.

(2) PRESCRIPTION COUNTER SPACE. A pharmacy shall have a prescription counter with a free working surface of 18 or more inches in width and at least 12 square feet in area. This free-working surface must be used only for the compounding and dispensing of prescriptions.

Phar 6.05 Sanitation. The professional service area of a pharmacy shall have a sink convenient and suitable for cleaning.
pharmaceutical equipment and supplied with hot and cold running water. Detergent and a waste disposal container also shall be provided in the professional service area.

**History:** Cf. Register, January, 1983, No. 325, eff. 2–1–83.

**Phar 6.06 Laws and other references.** The professional service area of a pharmacy shall have equipment of appropriate design and size for the intended pharmacy practice and shall have all of the following:

1. The latest available or immediately accessible version of federal and state pharmacy laws consisting of:
   - Drug enforcement administration regulations, 21 CFR 1300 to end.
   - Wisconsin pharmacy laws, ch. 450, Stats.
   - Wisconsin controlled substances act, ch. 961, Stats.
   - Wisconsin administrative code, rules of the pharmacy examining board.

2. References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

3. The telephone number of a poison center. This number shall be conspicuously posted in the prescription department.

4. The professional service area shall have a refrigerator adequate for the storage of biological and other drugs requiring refrigeration.

5. The professional service area shall have sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment.

6. Controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft.

**History:** Cf. Register, January, 1983, No. 325, eff. 2–1–83.

**Phar 6.07 Storage.** (1) The professional service area shall have a refrigerator adequate for the storage of biological and other drugs requiring refrigeration.

2. The professional service area shall have sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment.

3. Controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft.

**History:** Cf. Register, January, 1983, No. 325, eff. 2–1–83.

**Phar 6.075 Temperature; Humidity.** (1) **Definitions.** In this section:

(a) “Business day” means a day the pharmacy is open for business.

(b) “Dry place” means a place that does not exceed 40% average relative humidity at 68 degrees Fahrenheit or the equivalent water vapor pressure at other temperatures.

(c) “Freezer” means a place in which the temperature is maintained between −13 and +14 degrees Fahrenheit.

(d) “Mean kinetic temperature” means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

(e) “Refrigerator” means a place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

2. **Storage.** Drugs shall be stored at appropriate temperature and under appropriate conditions, including in a dry place, according to the manufacturer recommendation or an official pharmaceutical compendium.

3. **Recording devices.** Manual, electromechanical or electronic temperature and humidity recording devices shall be placed within the storage space to accurately determine the area’s temperature and humidity.

4. **Frequency.** The temperature of the refrigerator, freezer and pharmacy shall be monitored at least once during each business day. A minimum and maximum temperature over the course of the time a pharmacy is closed shall be obtained.

5. **Records.** Temperature and humidity records shall be maintained for a minimum of 5 years.

6. **Dispensing of safe drugs.** The pharmacist shall use professional judgment, including consideration of the mean kinetic temperature, to determine whether a drug is safe to be dispensed.

**History:** CR 16−077; cr. Register November 2017 No. 743, eff. 12−1−17; corrections in (1) (b) and (c), (6) made under s. 35.17, Stats., Register November 2017 No. 743.

**Phar 6.08 Security.** A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

**History:** Cf. Register, December, 1998, No. 516, eff. 1–1–99; CR 05−001; am. Register August 2005 No. 596, eff. 9–1–05; CR 09−098; am. Register May 2010 No. 653, eff. 6–1–10.
Board of Pharmacy

Chapter 855

Division 41
OPERATION OF PHARMACIES (AMBULATORY AND RESIDENTIAL DRUG OUTLETS)

855-041-1036
Proper Storage of Drugs

(1) A pharmacy must maintain proper storage of all drugs. This includes, but is not limited to the following:

(a) All drugs must be stored according to manufacturer's published or USP guidelines.

(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.

(d) A pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.

(2) A pharmacy must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).

(a) All drug refrigeration systems must:

(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.

(B) Utilize a centrally placed, accurate, and calibrated thermometer;

(C) Be dedicated to pharmaceuticals only; and

(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.

(b) A pharmacy must adhere to a monitoring plan, which includes, but is not limited to:

(A) Documentation of training of all personnel;

(B) Maintenance of manufacturer recommended calibration of thermometers;

(C) Maintenance of records of temperature logs for a minimum of three years;

(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;

(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan; and

(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment.
(3) Vaccine Drug Storage:

(a) A pharmacy that stores vaccines must comply with section two of this rule and the following:

(A) Vaccines must be stored in the temperature stable sections of the refrigerator;

(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;

(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;

(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and

(E) Must adhere to a written quality assurance process to avoid temperature excursions.

(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.

Statutory/Other Authority: ORS 689.205 & 689.325
Statutes/Other Implemented: ORS 689.155
History:
BP 1-2017, f. & cert. ef. 2-23-17
BP 3-2015, f. 7-1-15, cert. ef. 1-1-16

Please use this link to bookmark or link to this rule.
PURPOSE: This rule establishes supervision requirements for Missouri licensed pharmacies.

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

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

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

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

(2) Except as otherwise provided in section (4) of this rule or by other applicable law, no prescription or medication order may be prepared, compounded, dispensed, handled or otherwise provided without a pharmacist on duty who is present within the pharmacy permit area and able to render immediate assistance and correct errors.

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

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

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

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

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

(3) Except as otherwise provided by law or this rule, pharmacy technicians and intern pharmacist shall be under the direct supervision and responsibility of a pharmacist at all times.
when assisting in the practice of pharmacy. Except as otherwise authorized by law or rule of the Board, pharmacy technicians may not perform any other task or function that requires the professional judgment of a pharmacist including, but not limited to:

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

(B) Performing the final medication inspection or verification required by 20 CSR 2220-2.010(1)(B) or 20 CSR 2220-2.400(8);

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

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

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

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

(G) Independently performing or overriding a drug utilization review;

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

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

(J) Administering vaccines or other medication;

(K) Modifying drug therapy;

(L) Accepting/Receiving a [new/initial] verbal controlled substance prescription or medication order;

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

(N) Any other task or function that requires the professional judgment of a pharmacist.

(4) Authorized Activities During a Pharmacist’s Temporary Absence. Except as otherwise authorized by law, intern pharmacists and pharmacy technicians may perform the following activities when a pharmacist is absent from the permit area:
(A) Pharmacist On Premises. Intern pharmacists and pharmacy technicians may continue to assist in the practice of pharmacy when a pharmacist is temporarily absent from the pharmacy permit area, provided the temporary absence does not exceed thirty (30) minutes and a pharmacist is still present on the pharmacy premises who is able to provide assistance in the event of an emergency.

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

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

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

(C) Notwithstanding any provision of this rule, no compounding may be performed without a pharmacist present within the pharmacy permit area and supervising.
### DEFINITION OF “SUPERVISION”

<table>
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| Florida | The Board discussed a tentative rule in 2014 that does not appear to have been finalized. The proposed language provided:  

(1) When a licensed pharmacist delegates a task or tasks to a registered pharmacy technician, those tasks must be performed under the direct supervision of the delegating pharmacist.  

(2) “Direct Supervision” means the physical or real-time act of oversight and management of a pharmacy technician’s work and work product by a licensed pharmacist. Registered pharmacy technicians must be in a direct line of sight and hearing either physically or via technological means that allow an on-site pharmacist to ensure the quality of the technician's work and work product. If a pharmacy is using technological means to supervise technicians, the pharmacy must have documented policies and procedures and other adequate safeguards to protect against patient harm, diversion, and privacy incidents. |
| Indiana | 856 IAC 1-1.1-5 "Supervision" defined  
Sec. 5. For purposes of this article, "supervision" means the physical or real-time act of oversight and management by a managing pharmacist, pharmacist in charge, or qualifying pharmacist of another individual's work or work product. Unless otherwise stated in this article, individuals practicing pharmacy must be directly supervised either through a direct line of sight and hearing, or via technological means that allow a supervisor to adequately ensure quality of care and patient services. In accordance with other sections in this article, if a facility is using technology to allow indirect supervision, they must have documented policies and procedures and other adequate safeguards to protect against patient harm, diversion, and privacy incidents.  

856 IAC 1-1.1-4 "Reasonable visual and vocal distance" defined  
Sec. 4. The standard for "reasonable visual and vocal distance", as found in IC 25-26-13-18(a)(4) of the Pharmacy Practice Act, can be met by a pharmacist being physically present within the licensed permitted area or by a means that provides for adequate supervision of technicians as individually approved by the board. |
| Maine | 14. Direct supervision. "Direct supervision" is the ability of a pharmacist to:  
- Oversee the activities of a pharmacy intern or pharmacy technician by being physically present within the same work area as the technician being supervised;  
- Direct the activities of a pharmacy intern or pharmacy technician |
who has no fixed workstation (e.g., visits individual patient rooms); or

- Oversee the activities of a pharmacy intern or pharmacy technician at a point of care location remote from the pharmacist in control of an automated pharmacy system. Such supervision shall be exercised via 2-way, real-time voice and video communication between the supervising pharmacist and the pharmacy technician.

“Direct supervision” includes activities performed by a pharmacy intern or pharmacy technician during the supervising pharmacist’s short-term absence from the workplace for meals or breaks.
20 CSR 2220-2.090 Pharmacist-in-Charge

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

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

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

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


#A6. **Rules Under Initial Review**

*(The Board will discuss potential changes for the following rules; Suggestions will be incorporated into a draft rule for discussion at a future meeting)*

- 20 CSR 2220-2.110 (PRN Refills)
- 20 CSR 2220-2.120 (Transfer of Rx Information for Refill)
- 20 CSR 2220-2.130 (Drug Repackaging)
- 20 CSR 2220-2.190 (Patient Counseling)
  - *Staff Research*
20 CSR 2220-2.110 PRN Refills

PURPOSE: This rule clarifies the board’s requirements for refills as needed so that the practicing pharmacists in Missouri will have adequate guidelines in this area.

(1) A pharmacist shall not fill or refill any prescription which was written more than one year before being presented to the pharmacist, unless the pharmacist consults with the prescriber and confirms—
(A) That the person for whom the drugs or medicines were prescribed is still under the prescriber’s care or treatment;
(B) That the prescriber desires for the person to continue receiving the drugs or medicines; or
(C) If the prescriber answers negatively in either case listed in subsection (1)(A) or (B), the pharmacist shall not fill or refill the prescription, even if the prescription authorizes refills as needed (PRN).

(2) If a pharmacist knows or has reason to believe that a person for whom a prescription has been written is not under the prescriber’s care or treatment at the time the prescription is presented for filling or refilling, the pharmacist shall consult with their prescriber and ascertain that the prescriber intends for the person to receive the drugs or medicines. The pharmacist shall do this no matter when the prescription originally was written and even if the prescription authorizes refills PRN.

(3) After the pharmacist has confirmed the information required in sections (1) and (2) of this rule, s/he shall record it in his/her records in a uniform fashion so as to make it readily available for verification by the board or its authorized agents.


PURPOSE: This rule defines record keeping required for transfer of prescription information for the purpose of refill.

(1) Prescription information shall be transferred for the purposes of refill between licensed pharmacies, provided the prescription information to be transferred meets all of the following criteria:
   (A) The prescription information indicates authorization by the prescriber for refilling;
   (B) The drug on the prescription information is not a Schedule II controlled substance;
   (C) The number of lawfully allowable refills has not been exceeded or the maximum allowable time limit has not been exceeded;
   (D) If the transfer involves a controlled substance, all information must be transferred directly between two (2) licensed pharmacists; and
   (E) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one (1)-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) When a prescription on record is transferred, the following record keeping is required:
   (A) The prescription record at the transferring pharmacy shall show all of the following:
       1. The word void must appear on the face of the invalidated prescription or be immediately voided within the electronic system when the prescription is transferred;
       2. The prescription record shall provide the name of the pharmacy to which it was transferred, the date of transfer and the identity of the transferring pharmacist; and
       3. If the transfer involves a controlled substance, the address and Drug Enforcement Administration (DEA) registration number of the pharmacy to which it was transferred and the full name of the pharmacist receiving the prescription information must be recorded;
   (B) The prescription record at the receiving pharmacy shall show all of the following, in addition to all other lawfully required information of an original prescription:
       1. The prescription record is a transferred prescription record from another licensed location;
       2. Date of original issuance;
       3. Date of original filling, if different from original issuance date;
       4. Original number of refills authorized on the original prescription and the number of remaining authorized refills;
       5. Date of last refill;
       6. Prescription label number;
       7. Identity of licensed pharmacy from which the record was transferred;
       8. The identity of the transferring pharmacist provided that pharmacies that share the same database and are under the same ownership may, instead of transferring prescriptions directly between two (2) pharmacists, transfer a prescription electronically by generating a computer-based report at the transferring pharmacy of any prescriptions that have been transferred out. This record shall be readily retrievable to
the transferring pharmacy and board representatives and comply with all of the
requirements of this rule, except that the requirement to document pharmacist identity
shall not be required unless otherwise required by federal law;
9. If the transfer involves a controlled substance, the address and DEA registration
number from the transferring pharmacy must be recorded; and
10. Any electronic transfer must maintain patient confidentiality in accordance with
20 CSR 2220-2.300; and
(C) A computerized transfer of prescription information between licensed pharmacies
for the purpose of refill shall meet all the requirements stated in sections (1) and (2) of
this rule.

(3) A pharmacy shall complete the transfer within one (1) business day of receiving the
request.

AUTHORITY: sections 338.100, 338.140, and 338.280, RSMo 2000.* This rule
originally filed as 4 CSR 220-2.120. Original rule filed April 16, 1985, effective Aug. 11,
2001. Moved to 20 CSR 2220-2.120, effective Aug. 28, 2006. Amended: Filed Feb. 6,

RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971,
1981.
20 CSR 2220-2.130 Drug Repackaging

PURPOSE: This rule establishes requirements for drug repackaging.

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

(1) A pharmacist or pharmacy may prepackage drugs for other than immediate dispensing purposes provided that the following conditions are met:

(A) Only products which will be directly provided to the patient may be prepackaged;

(B) Containers utilized for prepackaging shall meet, as a minimum requirement, that of Class B container standards as referenced by the United States Pharmacopoeia (USP), which has been incorporated herein by reference. Where applicable, light sensitive containers shall be used;

(C) The maximum expiration date allowed for prepacked drugs shall be the manufacturer’s expiration date or twelve (12) months, whichever is less; and

(D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

(2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer’s container and is placed in a dispensing container for other than immediate dispensing to a patient.


20 CSR 2220-2.190 Patient Counseling

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

(1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist’s immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained. If the patient or caregiver is not available, then a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied with the medication so that the patient or caregiver may contact the pharmacist for counseling when necessary. In situations where automated pick-up systems are used for providing refill prescriptions to patients, the offer to counsel may be provided within the information provided by the kiosk to the patient during the processing phase prior to release of the medication to the patient. The elements of counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

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

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

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

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


Alabama:

680-X-2-.21. PATIENT COUNSELING.

(1) Pharmacists, because of their strategic position in the health care system, have traditionally provided drug information to their patients and to other health care professionals. In the best interest of the public health, the patient must be offered counseling for all new prescriptions and, where appropriate, for refill prescriptions. The offer to counsel shall be made by the pharmacist or the pharmacist's designee in a face to face oral communication with the patient, or the patient’s representative, unless in the professional judgment of the pharmacist, it is deemed inappropriate or unnecessary. If it is deemed inappropriate or unnecessary by the pharmacist, it would be permissible for the offer to counsel to be made in a written communication, by telephone, or in a manner determined by the pharmacist to be appropriate. Said counseling must be performed by the pharmacist or properly supervised pharmacist intern. A printed statement shall be included with every prescription listing the pharmacy's telephone number, for the patient to call with questions about their medication.

(2) Each new prescription and, where appropriate, refill prescription, should be reviewed for, but not limited to, the following:
(a) therapeutic duplication;
(b) drug-disease contraindication where indicated;
(c) drug-drug interaction;
(d) incorrect dosage/duration;
(e) drug allergy interactions; and
(f) clinical abuse/misuse.

(3) Pharmacists may discuss, but are not limited to, the following:
(a) Name and description of the medication;
(b) Dosage form, dosage, route of administration and duration of therapy;
(c) Special directions, precautions for preparation, administration and use by the patient;
(d) Common severe side effects, adverse effects or interactions, and therapeutic contraindications;
(e) Techniques for self monitoring;
(f) Proper storage;
(g) Refill information; and
(h) Action in the case of missed dose.

(4) Pharmacists or the pharmacist's designee, in a face to face communication, in institutional settings, shall offer to give an oral consultation with all new prescriptions and, where appropriate, for refill prescriptions dispensed to homeward-bound patients or the patient’s representative. Said counseling must be performed by the pharmacist or properly supervised pharmacist intern. If the patient or the patient’s representative are unavailable, the pharmacist shall make known the fact that a consultation is available and how he/she may be reached.

http://www.albop.com/PDF%20Files/act205_08.pdf
Alaska:

Sec. 08.80.480. DEFINITIONS.

(19) “patient counseling” means the communication by the pharmacist of information, as defined in the regulations of the board, to the patient or care giver in order to improve therapy by ensuring proper use of drugs and devices;

12 AAC 52.585. MANDATORY PATIENT COUNSELING.

(a) Before dispensing a prescription for the first time for a new patient of the pharmacy, a prescription for a new medication for an existing patient of the pharmacy, or a change in the dose, strength, route of administration, or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy, the pharmacist or pharmacy intern providing prescription services shall personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgment. The counseling may include

1. the name and description of the prescribed drug;
2. the dosage and the dosage form;
3. the method and route of administration;
4. the duration of the prescribed drug therapy;
5. any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;
6. common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;
7. patient techniques for self-monitoring of the drug therapy;
8. proper storage;
9. prescription refill information; and
10. the action to be taken in the event of a missed dose.

(b) A pharmacist shall counsel the patient or the patient’s agent face-to-face. If face-to-face counseling is not possible, a pharmacist shall make a reasonable effort to provide the counseling by use of a telephone, two-way radio, or in writing. In place of a pharmacist’s own written information regarding a prescribed drug, the pharmacist may use abstracts of the Patient United States Pharmacopoeia Drug Information or comparable information.

(c) This section does not apply to a pharmacist who dispenses drugs for inpatient use in a hospital or other institution if the drug is to be administered by a nurse or other appropriate health care provider.

(d) This section does not require a pharmacist to provide patient counseling when a patient or the patient’s caregiver refuses the counseling.

https://www.commerce.alaska.gov/web/portals/5/pub/PharmacyStatutes.pdf
Arkansas:

09-00-0001--PATIENT INFORMATION, DRUG USE EVALUATION, AND PATIENT COUNSELING

The intent of this regulation is to improve pharmaceutical care by defining basic standards of care. Pharmacy care/pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: (1) cure of disease, (2) elimination or reduction of a patient's symptomatology, (3) arresting or slowing a disease process, or (4) preventing a disease or symptomatology.

Pharmaceutical care (clinical pharmacy) involves four major functions on behalf of the patient: (1) identifying potential and actual drug-related problems, (2) resolving actual drug related problems, (3) preventing potential drug-related problems, and (4) optimizing patient therapy outcomes. It is recognized that the patient might be best served if medication is not provided.

(a) Patient information (profile)
In order to effectively counsel patients, the pharmacist must, through communication with the patient or caregiver, make a reasonable effort to obtain, record, and maintain the following information for each patient. It is recognized that most of this can be obtained using pharmacy technicians and designed forms, etc.
(1) Name, address, telephone number;
(2) Date of birth (age);
(3) Gender;
(4) Medical history
(A) Significant patient health problems known to the pharmacist;
(B) Prescription drug reactions/prescription drug allergies;
(C) List of prescription medications and legend drug administration devices known to the pharmacist.
(5) Transitory patients or situations where the pharmacy will only provide medication one time
In obtaining patient information, if the pharmacist knows or is informed by the patient that this is a one-time situation, the pharmacist may forego the above requirement to record and maintain the information.
(6) Pharmacist comments

(b) Drug use evaluation for new and refill prescriptions
Drug use evaluation or drug utilization review includes the following activities:
(1) The pharmacist shall evaluate the prescription or medication order for:
(A) Reasonable dose and route of administration;
(B) Reasonable directions for use.
(2) The pharmacist shall evaluate medication orders and patient information for:
(A) Duplication of therapy - is the patient taking the same or similar medication(s)?
(B) Prescription drug-prescription drug interactions;
(C) Proper utilization (over or under utilization);
(D) Known drug allergies.
(3) Drug-drug contraindications as defined by the Board. (Is this medication contraindicated with another medication the patient is taking?)
(4) It is recognized that the ultimate decision to use the medication or not use the medication rests with the physician who has more complete patient information. It is the pharmacist's responsibility to monitor the patient's medication therapy in the areas addressed in this regulation and inform the physician of the suspected problem.
(5) If a problem is suspected and the physician is informed, the pharmacist shall document the process.

(c) Patient counseling.
(1) A pharmacist shall counsel the patient or caregiver "face to face" if the patient or caregiver is in the pharmacy. If not, a pharmacist shall make a reasonable effort to counsel the patient or caregiver;
(2) Alternative forms of patient information may be used to supplement, but not replace face-to-face patient counseling;
(3) Patient counseling, as described herein, shall also be required for outpatients of hospitals and institutions when medications are dispensed on discharge from the hospital or institution.
(4) Patient counseling as described in this regulation shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer the medication. However, the pharmacist shall provide drug therapy counseling if it is when professionally deemed to be appropriate and when medications are provided by the pharmacy, and when a pharmacist is on duty and a patient is discharged from the hospital or institution.
(5) The pharmacist shall maintain and make available to all patients appropriate patient-oriented reference materials USP-DI or *Facts and Comparisons Patient Drug Facts* or an equivalent or better publication as determined by the Board.
(6) It is recognized that the ultimate decision to not provide patient counseling rests with the physician. If the physician in specific instances (blanket requests not accepted) requests that information NOT be provided to the patient and gives reason, the pharmacist should honor that request in almost all instances.

(d) "Patient counseling" shall mean the effective communication by the pharmacist of information, as defined in this act to the patient or caregiver, in order to improve therapeutic outcome by encouraging proper use of prescription medications and drug delivery devices.
(1) For original prescription medication orders, (excluding renewed or updated prescriptions the patient has been recently taking) and orders for legend devices, specific areas of counseling shall include:
(A) Name and general description of the medication dispensed, i.e. antibiotic, antihistamine, blood pressure medicine, etc.
(B) Name, general description and directions for use of drug delivery devices, i.e., insulin syringes, morphine pump, etc. (C) Explanation of route of administration, dosage, times of administration, and continuity of therapy;
(D) Special directions for storage as deemed necessary by the pharmacist;
(E) If the drug has been determined to have a significant side effect by the Board of Pharmacy, the patient shall be properly counseled to the extent deemed necessary by the pharmacist.
(F) When the prescription drug dispensed has a significant side effect, if taken with over-the-counter drugs, the pharmacist should counsel the patient about that interaction. (Example: coumadin with aspirin)

(G) If the prescription medication is significantly affected by food or diet, the pharmacist should so advise the patient. (Example: tetracycline with milk or food)

(H) The pharmacist shall inform the patient or caregiver that he/she is available to answer questions about medications or general health information.

(2) Refills--On refills the pharmacist shall present the opportunity for the patient or caregiver to ask questions. However, counseling on refills is not required except when needed in the professional judgment of the pharmacist.

California:

1707.2 Duty to Consult.
(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:
(1) upon request; or
(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
   (A) whenever the prescription drug has not previously been dispensed to a patient; or
   (B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.
(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice: of his or her right to request consultation; and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.
(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:
(1) directions for use and storage and the importance of compliance with directions; and
(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:
(1) the name and description of the medication;
(2) the route of administration, dosage form, dosage, and duration of drug therapy
(3) any special directions for use and storage;
(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
(5) prescription refill information;
(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.
Delaware:

1.0 Pharmacist Licensure Requirements
"Patient Counseling" means an oral communication process between a pharmacist, or a registered intern or a pharmacy student working under the direct supervision of a pharmacist, and a patient, in which the pharmacist obtains information from the patient and the patient’s pharmacy records, assesses that information and provides the patient with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.

5.2 Patient Counseling
5.2.1 Prior to dispensing a prescriptive medication to a new patient, a new medication to an existing patient or a medication that has had a change in the dose, strength, route of administration or directions for use, a pharmacist, or a registered intern or pharmacy student working under the direct supervision of a pharmacist, shall provide verbal counseling to the patient on pertinent medication information. The counseling may include, but not be limited to the following:
5.2.1.1 the name and description of the prescribed drug;
5.2.1.2 the dosage and the dosage form;
5.2.1.3 the method and route of administration;
5.2.1.4 the duration of the prescribed drug therapy;
5.2.1.5 any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;
5.2.1.6 common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;
5.2.1.7 patient techniques for self-monitoring of the drug therapy;
5.2.1.8 proper storage and appropriate disposal methods for unwanted or unused medications;
5.2.1.9 prescription refill information;
5.2.1.10 the action to be taken in the event of a missed dose; and
5.2.1.11 current over-the-counter medication use.
5.2.2 This section does not apply to a pharmacist dispensing drugs for inpatient use in a hospital or other institution where the drug is to be administered by a nurse or other appropriate health care provider.
5.2.3 Nothing in this section requires a pharmacist or pharmacy intern or student participating in an approved College of Pharmacy coordinated practical experience program and working under the direct supervision of a pharmacist, to provide patient counseling when a patient refuses the counseling. There must be a record in a uniform place that documents a patient's acceptance or refusal of counseling.
5.2.4 If the dispensed prescription is delivered by an agent of the pharmacy when the pharmacist is not present (i.e. home delivery, pharmacist off duty and non-resident pharmacies), or if an agent is picking up the prescription for the patient, written or printed information shall be included with the prescription. The patient or his/her agent shall be provided with the pharmacist’s contact information and informed that the pharmacist will be available for consultation.

Iowa:

657—6.14 (155A) Patient counseling and instruction.
Every general pharmacy located in Iowa shall post in every prescription pickup area, including in every drive-through prescription pickup lane, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any new prescriptions dispensed to the patient. The board shall provide a general pharmacy with the required signage. A pharmacy that provides no direct patient access to the pharmacy department, commonly referred to as a “closed-door pharmacy,” shall not be required to post the counseling notice.

6.14(1) Counseling required. Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy including but not limited to a change of dose, directions, or drug formulation, and following a prospective drug use review pursuant to 657—8.21(155A), a pharmacist shall counsel each patient or patient’s caregiver. An offer to counsel shall not fulfill the requirements of this rule. Patient counseling shall be on matters which, in the pharmacist’s professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

a. The name and description of the drug;
b. The dosage form, dose, route of administration, and duration of drug therapy;
c. Intended use of the drug, if known, and expected action;
d. Special directions and precautions for preparation, administration, and use by the patient;
e. Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
f. Techniques for self-monitoring drug therapy;
g. Proper storage;
h. Prescription refill information;
i. Action to be taken in the event of a missed dose;
j. Pharmacist comments relevant to the individual’s drug therapy including any other information peculiar to the specific patient or drug.

6.14(2) Instruction. A pharmacist may instruct patients and demonstrate procedures for self-monitoring of medical conditions and for self-administration of drugs.

6.14(3) Counseling area. A pharmacy shall contain an area which is suitable for confidential patient counseling. Such area shall:

a. Be easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;
b. Be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

6.14(4) Oral counseling not practicable. If in the pharmacist’s professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. “Not practicable” refers to patient variables including, but not limited to, the absence of the patient or patient’s caregiver, the patient’s or caregiver’s hearing impairment, or a language barrier. “Not practicable” does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume. Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone.
or collect telephone call. A combination of oral counseling and alternative forms of counseling is encouraged.

6.14(5) Exception. Patient counseling, as described above, shall not be required for inpatients of an institution where other licensed health care professionals are authorized to administer the drugs.

6.14(6) Refusal of consultation. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient’s or caregiver’s refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist’s attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

Kansas:

68-2-20 Pharmacist's function in filling a prescription.

(3) when appropriate, provide alternative forms of patient information to supplement verbal patient counseling. These supplemental forms of patient information may include written information, leaflets, pictogram labels, video programs, and auxiliary labels on the prescription vials. However, the supplemental forms of patient information shall not be used as a substitute for the verbal counseling required by this regulation;

(4) encourage proper patient drug utilization and medication administration. The pharmacist shall counsel the patient or patient’s agent on those elements that, in the pharmacist’s professional judgment, are significant for the patient. These elements may include the following:
(A) The name and a description of the prescribed medication or device;
(B) the dosage form, dosage, route of administration, and duration of therapy;
(C) special directions and precautions for preparation, administration, and use by the patient;
(D) common side effects, adverse effects or interactions, or therapeutic contraindications that could be encountered; the action required if these effects, interactions, or contraindications occur; and any activities or substances to be avoided while using the medication;
(E) techniques for self-monitoring drug therapy;
(F) proper storage requirements; and
(G) action to be taken in the event of a missed dose; and

(5) expressly notify the patient or the patient’s agent if a brand exchange has been exercised.

d) Nothing in this regulation shall be construed to require a pharmacist to provide the required patient counseling if either of the following occurs:
(1) The patient or the patient’s agent refuses counseling.
(2) The pharmacist, based upon professional judgment, determines that the counseling may be detrimental to the patient’s care or to the relationship between the patient and the patient’s prescriber.

e) Each pharmacist shall make a reasonable effort to ensure that any prescription, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized prescriber.

Kentucky:

201 KAR 2:210. Patient records and patient counseling.

Section 2. Patient Counseling.
(1) The pharmacist shall offer to counsel a patient on matters which he believes will optimize drug therapy with each patient or caregiver:
   (a) Upon the presentation of an original prescription order; and
   (b) On refill prescriptions, as professional discretion dictates.

(2) (a) The offer shall be made by the pharmacist in a face-to-face communication with the patient or caregiver, unless, in the professional judgment of the pharmacist, it is deemed impractical or inappropriate.
   (b) If deemed impractical or inappropriate, the offer to counsel may be made:
       1. By the pharmacist designee;
       2. In written communication;
       3. By telephone through access to a telephone service that is toll-free for long distance calls, unless the primary patient population is accessible through a local, measured, or toll-free exchange; or
       4. In another manner determined by the pharmacist to be appropriate.

(3) Patient counseling shall be:
   (a) In person when practical; or
   (b) With reasonable effort, by telephone.

(4) The pharmacist shall include the following elements of patient counseling that he has determined are appropriate:
   (a) The name and description of the drug;
   (b) The dosage form, dose, route of administration, and duration of therapy;
   (c) Special directions and precautions;
   (d) Common and clinically significant adverse effects, interactions, or contraindications that may be encountered, including their avoidance and the action required should they occur;
   (e) Techniques for self-monitoring of drug therapy;
   (f) Proper storage;
   (g) Refill information;
   (h) Action to be taken in event of a missed dose;
   (i) His comments relevant to the individual's therapy; and
   (j) Any other information peculiar to the specific patient or drug.

(5) If a pharmacist determines that it is appropriate, he may supplement patient counseling with additional forms of patient information, such as:
   (a) Written or printed information leaflets;
   (b) Pictogram labels; and
   (c) Video programs.

(6) Mail-order pharmacies shall be subject to the same counseling requirements as any other pharmacy.

Louisiana:

§1164. Definitions
(31) "Patient counseling" means the communication by a pharmacist of information, as defined by the regulations of the board, to the patient or caregiver, in order to ensure proper use of drugs and devices.

§517. Patient Counseling
A. Patient counseling means the effective communication by a pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices.

B. Minimum Requirements. At a minimum, the pharmacist should be convinced that the patient or caregiver is informed of the following:
1. name and description of the medication;
2. dosage form, dosage, route of administration, and duration of therapy;
3. special directions and precautions for preparation, administration, and use by the patient;
4. common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required in the event of their occurrence;
5. techniques for self-monitoring drug therapy;
6. proper storage of the medication;
7. prescription refill information, if any; and
8. the action to be taken in the event of a missed dose.

C. The pharmacist may supplement oral information with written information, but shall not use written information alone to fulfill the counseling requirement.

D. Patient Information.
1. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:
   a. name, address, and telephone number;
   b. date of birth (or age) and gender;
   c. allergies/drug reactions, disease state(s); and
   d. current list of all medications.

E. Communication to the Patient.
1. A pharmacist shall counsel the patient or caregiver “face-to-face” when possible or appropriate. If it is not possible or appropriate to counsel the patient or caregiver “face-to-face”, then a pharmacist should counsel the patient or caregiver by using alternative methods. The pharmacist shall exercise his professional judgment in the selection of alternative methods, including but not limited to, telephonic or electronic communication with the patient or caregiver.
2. A pharmacist shall provide patient counseling to patients discharged from hospitals and/or other institutions, where applicable. However, counseling shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer medication(s).
3. The pharmacist shall maintain appropriate patient-oriented drug information materials for use by the patient upon request.
F. Waiver. No pharmacist or pharmacy may solicit or encourage blanket waivers for patient counseling. However, nothing in this regulation shall prohibit the patient or caregiver from declining patient counseling.

**Minnesota:**

**6800.0910 PATIENT ACCESS TO PHARMACIST.**

Subpart 1. **Patient consultation procedure required.** Each licensed pharmacy in Minnesota required to provide patient counseling under this part must develop and maintain a written patient consultation procedure providing for direct oral communication between the patient and the pharmacist designed to improve the patient's understanding of and compliance with the patient's drug therapy to enhance or optimize the outcome of the patient's drug therapy.

Subp. 2. **Description of procedure.** When dispensing a filled prescription for a patient, a pharmacist must consult with the patient or the patient's agent or caregiver and inquire about the patient's understanding of the use of the drug according to this part.

A. Upon receipt of a new prescription, following a review of the patient's record, a pharmacist shall personally initiate discussion of matters which in the professional judgment of the pharmacist will enhance or optimize drug therapy with each patient or the agent or caregiver of the patient. The discussion shall be in person, whenever applicable, may be supplemented with written material, and shall include appropriate elements of patient counseling. These elements include the following:

1. the name and description of the drug;
2. the dosage form, dose, route of administration, and duration of drug therapy;
3. intended use of the drug and expected action;
4. special directions and precautions for preparation, administration, and use by the patient;
5. common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
6. techniques for self-monitoring of drug therapy;
7. proper storage;
8. prescription refill information;
9. action to be taken in the event of a missed dose; and
10. pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

B. The pharmacist must counsel the patient on a refilled prescription if deemed necessary according to the pharmacist's professional judgment. The consultation must be in person whenever applicable.

A pharmacist may vary or omit the patient information if, in the pharmacist's professional judgment, the variation or omission serves the best interest of the patient because of the particular individual circumstances involved. If there is any material variation from the minimal information required by this subpart in the information provided or, if consultation is not provided, that fact and the circumstances involved shall be noted on the prescription, in the patient's records, or in a specially developed log.

Personal communication by the pharmacist is not required for inpatients of a hospital or other institution, such as a licensed nursing home, where other licensed health care professionals are authorized to administer the drugs, or where a patient or patient's agent or caregiver has expressed a desire not to receive the consultation. When a new filled prescription or a refilled prescription for which counseling is required is being mailed or delivered to the patient by common carrier or
delivery services, the consultation must still be provided but may be accomplished by providing
written information to the patient regarding the medication being dispensed and the availability of
the pharmacist to answer questions, and through the provision of a toll-free phone number for long
distance calls.
Nothing in this part shall prohibit pharmacists from charging for these services.

https://www.revisor.mn.gov/rules/?id=6800&version=2017-08-21T10:21:34-05:00&format=pdf
Mississippi:

DEFINITIONS:

"Patient Counseling" shall mean the oral communication by a pharmacist of information to the patient or care giver to improve therapeutic outcomes by optimizing proper use of prescription drugs or devices. Alternative forms of patient information may be used to supplement verbal patient counseling when appropriate. Examples to include written information leaflets, pictogram labels, video programs, auxiliary labels on the prescription vial, etc.

ARTICLE VIII RESPONSIBILITY OF PHARMACIST/PHARMACIST CARE

4. Patient Counseling:
A. Upon receipt of an outpatient prescription drug order and following a review of the patient's record, it is the pharmacist or the pharmacist's agent's responsibility to make the offer to discuss matters which are deemed significant in the pharmacist's professional judgment. The pharmacist must provide the patient counseling. If patient or caregiver is not available, the pharmacist shall make known the fact that patient counseling is available and how he/she may be reached. Such discussion may include the following:
   (1) Name and description of the drug;
   (2) Dosage form, dose, route of administration, and duration of therapy;
   (3) Intended use of the drug and expected action;
   (4) Special directions and precautions for preparation, administration, and use by the patient;
   (5) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
   (6) Techniques for self-monitoring drug therapy;
   (7) Proper storage;
   (8) Prescription refill information;
   (9) Action to be taken in the event of a missed dose; and
   (10) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

B. Alternative forms of patient information may be used to supplement verbal patient counseling when appropriate, such as written information, leaflets, pictogram labels, video programs, auxiliary labels on the prescription vials, etc.

C. Patient counseling, as described above and defined in the Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

D. A pharmacist that dispenses prescriptions that are to be delivered to the patient or the patient's caregiver by U.S. Mail, UPS, Federal Express, or any other carrier or by any employee or agent of the pharmacy shall comply with the following:
   (1) Provide printed information with the delivery which supplies at a minimum the name, address and telephone number of the dispensing pharmacist and all information as outlined in paragraph 4., (A), of this ARTICLE.
E. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

F. A pharmacist may refuse to fill a prescription for a variety of reasons outlined within these regulations. Additionally, a pharmacist may decline to fill or refill a prescription or provide a service when the costs of providing those products or services exceeds the reimbursement obtained from a third-party payer. If a pharmacist declines to fill a prescription or provide a service because the costs associated with supplying the product or service exceeds the reimbursement for the product or service, he/she shall provide the patient with a list of pharmacies in the area that may provide the product or service.

Montana:

24.174.903 Patient Counseling

(1) Upon receipt of a new prescription drug order or refill prescription drug order if deemed necessary by the pharmacist, and following a review of the patient's record, a pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling. Such elements may include the following:
   (a) the name and description of the drug;
   (b) the dosage form, dose, route of administration, and duration of drug therapy;
   (c) intended use of the drug and expected action;
   (d) special directions and precautions for preparation, administration, and use by the patient;
   (e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
   (f) techniques for self-monitoring drug therapy;
   (g) proper storage;
   (h) prescription refill information;
   (i) action to be taken in the event of a missed dose; and
   (j) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Each pharmacy shall have at least one area that offers appropriate visual and auditory patient confidentiality for patient counseling.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(4) Patient counseling, as described above and defined in this Act shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s). Any pharmacist dispensing medication to be self-administered outside an institution shall comply with all patient counseling statutes and rules.

(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A record of the refusal shall be maintained by the pharmacist.

Nebraska:

38-2830. Patient counseling, defined. Patient counseling means the verbal communication by a pharmacist, pharmacist intern, or practitioner, in a manner reflecting dignity and the right of the patient to a reasonable degree of privacy, of information to the patient or caregiver in order to improve therapeutic outcomes by maximizing proper use of prescription drugs and devices and also includes the duties set out in section 38-2869.

38-2869. Prospective drug utilization review; counseling; requirements. (1)(a) Prior to the dispensing or the delivery of a drug or device pursuant to a medical order to a patient or caregiver, a pharmacist shall in all care settings conduct a prospective drug utilization review. Such prospective drug utilization review shall involve monitoring the patient-specific medical history described in subdivision (b) of this subsection and available to the pharmacist at the practice site for:
(i) Therapeutic duplication;
(ii) Drug-disease contraindications;
(iii) Drug-drug interactions;
(iv) Incorrect drug dosage or duration of drug treatment;
(v) Drug-allergy interactions; and
(vi) Clinical abuse or misuse.
(b) A pharmacist conducting a prospective drug utilization review shall ensure that a reasonable effort is made to obtain from the patient, his or her caregiver, or his or her practitioner and to record and maintain records of the following information to facilitate such review:
(i) The name, address, telephone number, date of birth, and gender of the patient;
(ii) The patient's history of significant disease, known allergies, and drug reactions and a comprehensive list of relevant drugs and devices used by the patient; and
(iii) Any comments of the pharmacist relevant to the patient's drug therapy.
(c) The assessment of data on drug use in any prospective drug utilization review shall be based on predetermined standards which are approved by the board.
(2)(a) Prior to the dispensing or delivery of a drug or device pursuant to a prescription, the pharmacist shall ensure that a verbal offer to counsel the patient or caregiver is made. The refusal of the verbal offer to counsel must be documented. The counseling of the patient or caregiver by the pharmacist shall be on elements which, in the exercise of the pharmacist's professional judgment, the pharmacist deems significant for the patient. Such elements may include, but need not be limited to, the following:
(i) The name and description of the prescribed drug or device;
(ii) The route of administration, dosage form, dose, and duration of therapy;
(iii) Special directions and precautions for preparation, administration, and use by the patient or caregiver;
(iv) Common side effects, adverse effects or interactions, and therapeutic contraindications that may be encountered, including avoidance, and the action required if such effects, interactions, or contraindications occur;
(v) Techniques for self-monitoring drug therapy;
(vi) Proper storage;
(vii) Prescription refill information; and
(viii) Action to be taken in the event of a missed dose.
(b) The patient counseling provided for in this subsection shall be provided in person whenever practical or by the utilization of telepharmacy which is available at no cost to the patient or caregiver.
(c) Patient counseling shall be appropriate to the individual patient and shall be provided to the patient or caregiver.
(d) Written information may be provided to the patient or caregiver to supplement the patient counseling provided for in this subsection but shall not be used as a substitute for such patient counseling.
(e) A verbal offer to counsel is not required when:
(i) The pharmacist, in his or her professional judgment, determines that patient counseling may be detrimental to the patient's care or to the relationship between the patient and his or her practitioner;
(ii) The patient is a patient or resident of a health care facility or health care service licensed under the Health Care Facility Licensure Act to whom prescription drugs or devices are administered;
(iii) A medical gas or a medical gas device is administered, dispensed, or distributed by a person described in subdivision (10) of section 38-2850; or
(iv) A device described in subsection (2) of section 38-2841 is sold, distributed, or delivered by a person described in subdivision (11) of section 38-2850.

http://dhhs.ne.gov/publichealth/Documents/Pharmacy.pdf
§ 131E-79.1. Counseling patients regarding prescriptions.
(a) Any hospital or other health care facility licensed pursuant to this Chapter or Chapter 122C of the General Statutes, health maintenance organization, local health department, community health center, medical office, or facility operated by a health care provider licensed under Chapter 90 of the General Statutes, providing patient counseling by a physician, a registered nurse, or any other appropriately trained health care professional shall be deemed in compliance with the rules adopted by the North Carolina Board of Pharmacy regarding patient counseling.

(b) As used in this section, "patient counseling" means the effective communication of information to the patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription medications and devices.

21 NCAC 46 .2504 PATIENT COUNSELING
(a) "Patient Counseling" shall mean the effective communication of information, as defined in this Rule, to the patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription medications, devices, and medical equipment. All provisions of this Rule shall apply to device and medical equipment permit holders, except Subparagraph (a)(8) of this Rule and except where otherwise noted. Specific areas of patient counseling include, but are not limited to, those matters listed in this Rule that in the exercise of the pharmacist's or device and medical equipment permit holder's professional judgment are considered significant:
(1) name, description, and purpose of the medication;
(2) route, dosage, administration, and continuity of therapy;
(3) special directions for use by the patient;
(4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(5) techniques for self-monitoring drug therapy;
(6) proper storage;
(7) prescription refill information; and
(8) action to be taken in the event of a missed dose.

(b) An offer to counsel shall be made on new or transfer prescriptions at the time the prescription is dispensed or delivered to the patient or representative. Ancillary personnel may make the offer to counsel, but the pharmacist must personally conduct counseling if the offer is accepted. Counseling by device and medical equipment permit holders must be conducted by personnel proficient in explaining and demonstrating the safe and proper use of devices and equipment. The person in charge shall be responsible for ensuring that all personnel conducting counseling are proficient in explaining and demonstrating the safe and proper use of devices and equipment and for documenting the demonstration of such proficiency. The offer shall be made orally and in person when delivery occurs at the pharmacy. When delivery occurs outside of the pharmacy, whether by mail, vehicular delivery or other means, the offer shall be made either orally and in person, or by telephone from the pharmacist to the patient. If delivery occurs outside of the pharmacy, the pharmacist shall provide the patient with access to a telephone service that is toll-free for long-distance calls. A pharmacy whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Counseling may be conducted by the provision of printed information in a foreign language if requested
by the patient or representative. Professional judgment shall be exercised in determining whether or not to offer counseling for prescription refills. An offer to counsel shall be communicated in a positive manner to encourage acceptance.

(c) In order to counsel patients effectively, a reasonable effort shall be made to obtain, record, and maintain significant patient information, including:

1. name, address, telephone number;
2. date of birth (age), gender;
3. medical history:
   A) disease state(s);
   B) allergies/drug reactions;
   C) current list on non-prescription and prescription medications, devices, and medical equipment.

A "reasonable effort" shall mean a good faith effort to obtain from the patient or representative the foregoing patient information. Ancillary personnel may collect, record, and obtain patient profile information, but the pharmacist or person in charge of the facility holding the device and medical equipment permit must review and interpret patient profile information and clarify confusing or conflicting information. Professional judgment shall be exercised as to whether and when individual patient history information should be sought from other health care providers.

(d) Once patient information is obtained, this information shall be reviewed and updated by the pharmacist or person in charge of the facility holding the device and medical equipment permit before each prescription is filled or delivered, typically at the point-of-sale or point of distribution to screen for potential drug therapy problems due to:

1. therapeutic duplication;
2. drug-disease contraindication;
3. drug-drug interactions, including serious interactions with prescription or over-the-counter drugs;
4. incorrect drug dosage or duration of drug treatment;
5. drug-allergy interactions; and
6. clinical abuse/misuse.

(e) Unless refused by the patient or representative, patient counseling shall be provided as follows:

1. counseling shall be "face to face" by the pharmacist, or personnel of a device and medical equipment permit holder when possible;
2. alternative forms of patient information may be used to supplement patient counseling;
3. patient counseling, as described in this Rule, shall be required for outpatient and discharge patients of hospitals, health maintenance organizations, health departments, and other institutions; however, compliance with this Rule in locations in which non-pharmacists are authorized by law or regulations to dispense may be accomplished by such authorized non-pharmacists; and
4. patient counseling, as described in this Rule, shall not be required for inpatients of hospitals or other institutions where a nurse or other licensed health care professional administers the medication(s).

(f) Pharmacists that distribute prescription medication by mail, and where the practitioner-pharmacist-patient relationship does not exist, shall provide counseling services for recipients of such medication in accordance with this Rule.

(g) Records resulting from compliance with this Rule, including documentation of refusals to receive counseling, shall be maintained for three years in accordance with Section .2300 of this Chapter.
(h) Personnel of device and medical equipment permit holders shall give written notice of warranty, if any, regarding service after the sale. The permit holder shall maintain documentation demonstrating that the written notice of warranty was given to the patient.

(i) Offers to counsel and patient counseling for inmates need not be "face to face", but rather, may be conducted through a correctional or law enforcement officer or through printed material. A pharmacist or a device and medical equipment permit holder dispensing drugs or devices or delivering medical equipment to inmates need not comply with Paragraph (c) of this Rule. However, once such patient information is obtained, the requirements of Paragraph (d) of this Rule shall be followed.

Ohio:

4729-5-22 Patient counseling.

(A) A pharmacist or the pharmacist's designee shall personally offer to provide the service of counseling pursuant to paragraph (B) of this rule to the patient or caregiver whenever any prescription, new or refill, is dispensed. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription or incorporated as part of documentation, in a conspicuous manner, that is included with the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

(B) In the event a patient or caregiver accepts an offer to counsel or requests counseling, a pharmacist, or an intern under the personal supervision of a pharmacist, shall counsel the patient or caregiver. Such counseling may include, but is not limited to, the following:

1. The name and description of the drug;
2. The dosage form, dose, strength, frequency, route of administration, and duration of drug therapy;
3. The intended use of the drug and the expected action;
4. Special directions and precautions for preparation, administration, and use by the patient;
5. Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;
6. Techniques for self-monitoring drug therapy;
7. Proper storage and disposal;
8. Prescription refill information;
9. Action to be taken in the event of a missed dose; and
10. The pharmacist's comments relevant to the individual's drug therapy, including other necessary information unique to the specific patient or drug.

(C) Other forms of information may be used when appropriate to supplement the counseling by the pharmacist or intern. Examples of forms that may be used include, but are not limited to, drug product information leaflets, pictogram labels, and video programs.

(D) Patient counseling shall not be required for inpatients of an institutional facility as defined in rule 4729-17-01 of the Administrative Code.

(E) Notwithstanding rule 4729-5-01 of the Administrative Code, "personal supervision", as used in paragraph (B) of this rule, means that a pharmacist is on the premises at all times and is aware of all counseling activities performed by the pharmacy intern. A pharmacist who has accepted responsibility for the supervision and training of a pharmacy intern is responsible for all acts performed by the pharmacy intern working under the pharmacist's supervision.

http://codes.ohio.gov/oac/4729-5-22
Oklahoma:

535:10-9-2. Counseling
Counseling shall be performed by the pharmacist when deemed appropriate in the pharmacist's professional judgement or when required by applicable federal or state laws or rules.
(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall assure that an offer is made to each patient or caregiver of such patient to discuss matters which will enhance or optimize drug therapy. Such discussion shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling. Such elements may include the following:
(A) the name and description of the drug;
(B) the dosage form, dose, route of administration, and duration of drug therapy;
(C) intended use of the drug, if known, and expected action;
(D) special directions and precautions for preparation, administration, and use by the patient;
(E) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(F) techniques for self-monitoring drug therapy;
(G) proper storage;
(H) prescription refill information;
(I) action to be taken in the event of a missed dose; and
(J) pharmacist comments on patient's drug therapy.

(2) The pharmacist shall be responsible to assure that a reasonable effort is made to obtain, record, and maintain patient information generated at the individual pharmacy.
(A) This information shall include:
(i) name, address, telephone number, date of birth or age, and gender;
(ii) individual history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
(iii) any additional comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.
(B) The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that such offer was accepted and that such counseling was provided;
(C) Such information may be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records.

(3) Alternative forms of information may be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(4) Patient counseling is not required on prescription refill requests, unless deemed appropriate in the pharmacist's professional judgement.

(5) Patient counseling, as described and defined in this section, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s). Outpatient pharmacies in hospitals are not exempt and counseling will be required for discharged patients exiting the hospital with prescription medication.

(6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.
(7) If a pharmacy is routinely filling prescriptions that are being shipped or delivered to patients in another state or if a pharmacy in another state is routinely filling and shipping prescriptions to patients in Oklahoma, the pharmacy will make a reasonable effort to call the patient and counsel by phone. A toll free phone number shall be provided for patients to call and interact with a pharmacist for drug information.

#A7. FY 2017 Annual Report
- Draft Report
States Attorney's Office, the United States Drug Enforcement Administration, the Missouri Bureau of Narcotics and Dangerous Drugs and Board staff.
DISCUSSION: Due to pending rule revisions, staff recommends issuing the revised Practice Guide in February 2018. Please provide any suggested comments/changes for incorporation into the final draft in February. Suggestions/comments are requested before January 20, 2018. A final draft will be returned for Board approval at the February meeting. Please note:

1. The CLIA waived testing language after D.10
2. The newly added Class-B section which primarily incorporates language from the Class-B draft guidance document.
MESSAGE FROM THE BOARD

The Missouri Board of Pharmacy is pleased to provide the Missouri Pharmacy Practice Guide. The Pharmacy Practice Guide is designed to increase licensee compliance by providing guidance on basic provisions of Missouri’s law governing pharmacy practice.

The Board has served Missouri citizens through the regulation and licensing of the pharmacy profession since 1909. The Board 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.

The Board’s mission is to serve and protect the public in the practice of pharmacy by providing an accessible, responsible and accountable regulatory system that:

- Protects the public;
- Licenses only qualified professionals; and
- Enforces practice standards.

Additional pharmacy resources and compliance materials are available on the Board’s website at http://pr.mo.gov/pharmacists. The Board also provides license and regulatory updates via e-alerts and the Board’s electronic newsletter. Interested parties can sign up for the Board’s newsletter and e-alerts at https://public.govdelivery.com/accounts/MODIFP/subscribers/new?preferences=true.

The Missouri Pharmacy Practice Guide is provided for informational purposes only and does not constitute a rule statement of general applicability or binding law. The Practice Guide does not constitute a comprehensive review of all governing law or controlled substance requirements. To ensure compliance, licensees should independently review Chapter 338, RSMo, 20 CSR 2220 and all applicable state and federal laws. Statutes/rules may have changed since the document was issued. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The Board expressly reserves the right to revise the contents as deemed appropriate or necessary. Questions regarding this document may be addressed to the Board office.
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A.1 GENERAL AUTHORITY

Pursuant to Chapter 338, of the Revised Statutes of Missouri, the Board has regulatory authority over the practice of pharmacy in Missouri which includes, but is not limited to, monitoring compliance, conducting investigations/inspections and licensing pharmacists, intern pharmacists, pharmacy technicians, pharmacies and drug distributors. The Board’s administrative rules are promulgated in Chapter 20 CSR 2220 of the Missouri Code of State Regulations.

The Missouri Bureau of Narcotics and Dangerous Drugs (“BNDD”) regulates controlled substance distribution in Missouri. However, the Board monitors and inspects compliance with applicable controlled substance drug laws. For controlled substance questions, contact BNDD at (573) 751-6321 or e-mail bndd@health.mo.gov. E-mail is preferred.

A.2 COMPLIANCE AND EDUCATION

The Board is committed to promoting voluntary compliance through education and awareness. A variety of free practice resources and compliance guides are available on the Board’s website. The Board also hosts periodic webinars to discuss emerging compliance issues and trends. Sign-up for the Board’s newsletter and e-alerts at https://public.govdelivery.com/accounts/MODIFP/subscriber/new to receive webinar notices and other regulatory updates, including notification of technician disciplinary actions.

A.3 DISCIPLINARY AUTHORITY

The Board may impose discipline if a licensee/registrant, or any officer, owner, pharmacist-in-charge or manager-in-charge, has committed any act identified in § 338.055.2. Grounds for disciplinary action include, but are not limited to:

1. Using a controlled substance or alcoholic beverage to an extent that such use impairs a licensee’s/registrant’s ability to practice;
2. Being finally adjudicated and found guilty, or entering a plea of guilty or nolo contendere, for any criminal offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated by Chapter 338, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude (this includes a suspended imposition of sentence or “SIS”);
3. Obtaining or attempting to obtain any fee or other compensation by fraud, deception or misrepresentation;
4. Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by Chapter 338;
5. Violating, or assisting or enabling any person to violate, Chapter 338 or any Board rule;
6. Assisting or enabling any person to practice or offer to practice without the required Board license, registration or permit;
7. Violating any professional trust or confidence;
8. Violating any state or federal drug law or regulation;
9. Intentionally substituting or changing the content, formula or brand of any drug prescribed without prior prescriber approval; or
10. Using any controlled substance unless it is prescribed, dispensed, or administered by an authorized health care provider. See § 338.055 for a list of all disciplinary grounds.
Disciplinary action may include, but is not limited to, public censure, probation, suspension or revocation. If revoked, the Board may prohibit a licensee from reapplying for licensure for up to seven (7) years.

### A.4 MANDATORY REPORTING OF DISCIPLINE/ADVERSE ACTIONS

The following disciplinary/adverse actions must be reported to the Board:

<table>
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<tr>
<th>STATUTE</th>
<th>WHO IS REQUIRED TO REPORT?</th>
<th>WHAT SHOULD BE REPORTED?</th>
<th>WHEN</th>
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<tbody>
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<td>§ 338.013</td>
<td>Licensed pharmacies &amp; hospitals</td>
<td>✓ Any final disciplinary action taken against a technician for conduct that may constitute grounds for discipline under § 338.055</td>
<td>Within fifteen (15) days after action/resignation.</td>
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<td>✓ <strong>Any technician</strong> who voluntary resigns if a complaint or report has been made against the technician which could have led to final disciplinary action and the actions alleged in the complaint/report are cause for discipline under § 338.055</td>
<td></td>
</tr>
<tr>
<td>§ 338.075</td>
<td>ALL licensees, registrants and permit holders</td>
<td>✓ Any final adverse action taken by another licensing state, jurisdiction or governmental agency against any license to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug distributor, drug manufacturer or drug outsourcing facility</td>
<td>Within seven (7) days of action</td>
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<td>✓ Any surrender of a license or authorization to practice as a pharmacist, pharmacy, drug distributor, technician, intern pharmacist or drug outsourcer</td>
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<td>✓ Any exclusion to participate in any state or federal funded health care program for fraud or abuse or for submitting any false/fraudulent claim for payment or reimbursement (e.g., Medicare, Medicaid or MoHealthNet).</td>
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</tr>
<tr>
<td>§ 383.133</td>
<td>Any entity that employs a pharmacist to provide health care services (<em>this includes, but is not limited to, pharmacies, hospitals, ambulatory surgical centers, long-term care facilities and nursing homes</em>)</td>
<td>✓ Any final disciplinary action against the pharmacist that might have led to disciplinary action under § 338.055</td>
<td>Within fifteen (15) days of the final disciplinary action/resignation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>✓ <strong>The voluntary resignation of any pharmacist against whom any complaints or reports have been made which might have led to disciplinary action.</strong></td>
<td></td>
</tr>
</tbody>
</table>

Interested parties should consult legal counsel to determine what actions/voluntary resignations constitute grounds for discipline under § 338.055. In the past, the Missouri Administrative Hearing Commission has found legal grounds for discipline under § 338.055, RSMo, for the following types of conduct:

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• Practicing without a license
• Falsifying prescriptions
• Altering a prescription without authorization
• Immunizing without a protocol
• Diverting medication
• Compounding for office stock
• Dispensing without a valid prescription
• Theft of merchandise, gift cards, food or other items
• Violating state/federal controlled substance laws
• Unsupervised technicians
• Unlicensed practice
• Impairment/Illegal drug use
• Disciplinary action by BNDD, DEA or another state/federal agency
• Allowing unlicensed technicians or interns to practice

This list is not exhaustive. Additional grounds for discipline exist under § 338.055, RSMo, that are not listed above. Note: Section 338.075 requires reporting of all disciplinary action or federal exclusions even if the conduct isn’t grounds for discipline under § 338.055.

Notifications/Reports can be filed online at http://pr.mo.gov/pharmacists-onlineservices.asp or mailed to: Missouri Board of Pharmacy, P.O. Box 625, Jefferson City, Missouri 65102. Online reporting is preferred.
B.1 GENERAL REQUIREMENTS

No person may perform, or offer to perform, the “practice of pharmacy” in the state of Missouri without a current and active Missouri pharmacist license. Section 338.010.1, RSMo, defines “the practice of pharmacy” as:

- Interpreting, implementing, and evaluating prescriptions/medication orders, including, handling or facilitating the dispensing of such orders;
- Providing medication therapy services, as defined by rules of the Board;
- Compounding, dispensing and labeling drugs/devices pursuant to a medical prescription order;
- Administering vaccines by protocol or administering medication by prescription drug order;
- Participating in drug selection and drug utilization reviews according to state law;
- Consulting with patients and other health care practitioners about the safe and effective use of drugs and devices; and,
- Offering or performing any act or service necessary in the conduct, operation, management and control of a pharmacy. [§ 338.010]

Pharmacist licensure is not required for legally registered practitioners of medicine, dentistry, podiatry, veterinary medicine or optometry that are lawfully compounding or dispensing their own prescriptions. [§ 338.010.1]

In addition to a Missouri pharmacist license, additional certification and/or Board notification is required for pharmacists performing the following services:

- Immunizing by Protocol (See Section I)
- Administering Medication By Prescription Order (See Section J)
- Medication Therapy Services (See Section K)

B.2 RENEWALS/CONTINUING EDUCATION

Pharmacist licenses are renewed biennially in even numbered years (e.g., 2018, 2020). To renew, pharmacists must file a renewal application with the required fee and complete 30 hours of approved continuing education (CE). [20 CSR 2220-7.080]. One continuing education unit (CEU) is the equivalent of ten clock hours of CE.

CE must have been earned from November 1st of the prior renewal year and October 31st of the current renewal year. For example, licensees renewing in 2018 must have completed 30 CE hours from November 1, 2016 to October 31, 2018. Although the CE deadline is October 31st, CE must be completed before a renewal is submitted. All CE must be provided by an ACPE accredited provider or approved by the Board in advance. Only non-ACPE courses have to be pre-approved. The Board will not approve non-ACPE classes that have already been taken.

Licensees should review 20 CSR 2220-7.080 for a complete listing of Missouri CE requirements. Additional CE information is provided in Appendix A. The Board randomly audits CE compliance. Proof of CE must be maintained in the licensee’s records for two renewal cycles and provided on request.

B.3 CHANGE OF ADDRESS/EMPLOYMENT

Pharmacists and pharmacy technicians are required to notify the Board of address and employment changes. Employment changes must be submitted no later than fifteen (15) days after the change. [20 CSR 2220-2.010(1)(Q), 20 CSR 2220-2.700(3)]. Address changes should be submitted as soon as possible to ensure
sufficient communication. Correspondence returned to the Board because of an incorrect address will not be resent until a correct address is provided. Address and employment changes may be submitted online at https://renew.pr.mo.gov/pharmacists-coa.asp.

B.4 JURY DUTY

Section 494.430.1(4), RSMo, allows a pharmacist to be excused from jury duty if he/she is providing health care services to patients and serving as a juror would be detrimental to patient health. This exemption is not automatic and must be granted by a judge.

B.5 MILITARY LICENSEES

A Missouri pharmacist license is not required for legally qualified pharmacists serving in the United States armed forces, or pharmacists employed by the U.S. government or any U.S. agency/bureau, who are engaged in the practice of pharmacy while in the discharge of their official duties. This exemption only applies to pharmacy services provided as part of the pharmacist’s federal/military duties or employment. A Missouri pharmacy license would be required if the pharmacist is practicing outside of his/her federal or military duties (e.g., independently practicing at a retail pharmacy). [§ 338.020.2, RSMo.]

Late Renewals/CE Exemption: A pharmacist may renew his/her license for no fee if the pharmacist’s license expired while on active duty in the U.S. armed services/Coast Guard/state militia, or expired while in training or education prior to being inducted into the military. [Section § 338.060.2] Renewal applications must be submitted within one (1) year after terminating the applicable military service, training or education. Similarly, § 41.946, RSMo, waives Missouri’s CE requirements for licensees who expire while completing military service.

To submit a late renewal or to request a CE exemption, pharmacists must provide an affidavit attesting that the pharmacist was engaged in military service as provided by § 338.060.2, RSMo. Alternatively, the Board will accept official discharge documentation. The affidavit/documentation must include:

- The pharmacist’s name,
- The date service/training/education began and ended, and
- The status of termination (e.g., completed, honorably discharged, etc.). Note: The late renewal allowance does not apply if dishonorably discharged.

For questions about military renewals/licensing, call (573) 751-0092 or e-mail pharmacist@pr.mo.gov.

Exam Reimbursement: Veterans may be eligible for reimbursement from Veterans Affairs for the Board’s licensing exam fees. Visit the Veterans Affairs website to learn more about how the GI Bill can pay the cost of a license or certification test or call 888-GIBILL-1 (888-442-4551), or for the hearing-impaired call 800-829-4833.
C.1 PHARMACY LICENSURE

No person or entity may open, establish, operate or maintain a pharmacy in the state of Missouri without a valid Missouri pharmacy permit. A pharmacy includes, but is not limited to, any place:

- Where the practice of pharmacy is offered or conducted or where the practice of pharmacy is provided by a pharmacist or someone acting under the pharmacist’s supervision or authority.
- Where drugs, chemicals, medicines, prescriptions, or poisons are compounded, prepared, dispensed, sold or offered for sale at retail;
- Where the words "pharmacist", "apothecary", “pharmacy”, "drugstore", "drugs" and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services; or
- Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons. [§ 338.210; 338.260]

C.2 PHARMACY CLASSIFICATIONS

The Board issues the following classes of pharmacy permits [§ 338.220, 20 CSR 2220-2.020(9)]:

<table>
<thead>
<tr>
<th>CLASS</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class A (Community/Ambulatory)</td>
<td>Required to provide pharmacy services to the general public (e.g., retail).</td>
</tr>
<tr>
<td>Class B (Hospital Pharmacy)</td>
<td>A pharmacy owned, managed, or operated by a hospital as defined by § 197.020 or a hospital clinic or facility under common control, management or ownership of the same hospital or hospital system. [§ 338.220.6]. * Licensure is not required for hospital pharmacies operating under the jurisdiction of the Missouri Department of Health and Senior Services. See section C.18 for additional information.</td>
</tr>
<tr>
<td>Class C (Long-Term Care)</td>
<td>Required for pharmacies dispensing drugs/devices to patients residing in a long-term care facility which would include a nursing home, retirement facility, mental care facility or any other facility that provides extended health care to resident patients. See also Section M.</td>
</tr>
<tr>
<td>Class D (Non-Sterile Compounding)</td>
<td>Required for pharmacies providing non-sterile compounding as defined by 20 CSR 2220-2.400(3), in batch quantities using bulk active ingredients. [See 20 CSR 2220-2.400].</td>
</tr>
<tr>
<td>Class E (Radiopharmaceutical)</td>
<td>Required for pharmacies preparing/dispensing radioactive drugs as defined by the Food and Drug Administration (FDA) to health care providers for treatment/diagnosis. Class-E pharmacies must maintain a qualified nuclear pharmacist. The nuclear pharmacist must be personally present and directly supervise all personnel assisting in drug preparation/dispensing. [See 20 CSR 2220-2.500].</td>
</tr>
<tr>
<td>Class F (Renal Dialysis)</td>
<td>Required for pharmacies dispensing renal dialysis solutions and other drugs/devices associated with dialysis care. Renal dialysis pharmacies may not be open to the general public and may only dispense renal dialysis solutions and renal dialysis associated drugs, supplies or devices. [See 20 CSR 2220-2.600].</td>
</tr>
<tr>
<td>Class G (Medical Gas)</td>
<td>Required for pharmacies providing oxygen and other prescription gases by prescription for therapeutic use.</td>
</tr>
<tr>
<td>Class H (Sterile Product Compounding)</td>
<td>Required for sterile compounding pharmacies, as defined by 20 CSR 2220-2.200.</td>
</tr>
</tbody>
</table>

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**CLASS** | **DESCRIPTION (CONT’D)**
--- | ---
Class I (Consultant) | Required for a location where the practice of pharmacy is conducted but which is not being used for the procurement, storage, possession or ownership of drugs.
Class J (Shared Service) | Required for pharmacies engaged in shared services with/for another pharmacy such as, filling/refilling medication, central fill services, drug utilization review or therapeutic interventions. *See Section C.19. [20 CSR 2220-2.650]*
Class K (Internet) | Required for pharmacies receiving, reviewing, preparing, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for new prescriptions originated from the internet for more than 90% of the pharmacy’s total new prescription volume on any day. *See the Ryan Haight Act for additional federal requirements.*
Class L (Veterinary) | Required for entities selling, dispensing, or filling a prescription only legend drug for animal use. *Note: Class A pharmacies may dispense medication for animal use without an additional Class L permit. See 20 CSR 2220-2.675 for Class L Veterinary requirements.*
Class M: Specialty (Bleeding Disorder) | Required for pharmacies providing blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders. *See 20 CSR 2220-6.100.* *See New Missouri Standards for Pharmacies Dispensing Blood-Clotting Therapies for additional guidance.*
Class N: Automated Dispensing System (Health Care Facility) | Required for pharmacies operating automated/mechanical systems in a health care facility to store, package or dispense medication. *See 20 CSR 2220-2.900.**
Class O: Automated Dispensing System (Ambulatory) | Required for pharmacies operating automated/mechanical systems in an ambulatory setting to store, package or dispense medication. *See 20 CSR 2220-2.900.**
Class P: Practitioner Office/Clinic | Required for pharmacies operating in a practitioner’s office/clinic. A pharmacy permit is not required for practitioner office dispensing to their own patients.**

**Final Board rules have not been promulgated.**

Pharmacies may only engage in the pharmacy activities allowed for the class(es) reflected on the pharmacy’s permit. To add or delete a class, a *Change of Classification Application* must be filed. Pharmacies may not function under an added class until the Board has issued a new permit reflecting the new classification.

✔ *Pharmacies must comply with all regulations pertaining to any class listed on the pharmacy’s permit even if they are not actually performing the activities. For example, a Class H Sterile Product pharmacy must comply with the Board’s sterile compounding rules even if the pharmacy isn’t currently compounding.*

C.3 NON-RESIDENT PHARMACIES

Pursuant to [20 CSR 2220-2.025](#), pharmacies located outside of Missouri may not ship, mail or deliver a filled prescription/medication order into Missouri without first obtaining a Missouri pharmacy permit.

To be eligible for licensure, a non-resident pharmacy must be located in the United States or a U.S. territory and have a current and active pharmacy license in the state/territory where the non-resident pharmacy is physically located. [20 CSR 2220-2.025](#). Non-resident pharmacies must designate a pharmacist-in-charge who will be personally responsible for supervising the pharmacy and who holds an active pharmacist
license in Missouri or in the non-resident pharmacy’s licensing state/territory. A non-resident pharmacy permit may not be renewed if does not hold a valid pharmacy license in their home state. [§ 338.270]

Note: For non-resident licensure exemptions see 20 CSR 2220-2.025(1).

C.4 APPLICATION REQUIREMENTS

Applicants for a pharmacy permit must file an application with the Board, pay the applicable fee and meet the following requirements:

- The pharmacy must designate and be under the supervision of a “pharmacist-in-charge”;
- Equipment and facilities must be operated in a manner that will not endanger the public health or safety;
- The pharmacy must be equipped with proper pharmaceutical and sanitation appliances;
- The pharmacy must be maintained in a clean, sanitary and orderly manner. Animals are not allowed in the pharmacy, except for service animals as defined by the American with Disabilities Act [20 CSR 2220-2.010(F)]; and
- Proposed/current operations must comply with Chapter 338 and all applicable state/federal law. [20 CSR 2220-2.010(1)(C) – (F), 20 CSR 2220-2.020]

Pharmacies may be owned by unlicensed persons/entities. However, the practice of pharmacy may only be conducted by licensed pharmacists.

✓ In-state pharmacies must pass a Board inspection prior to licensure. Non-resident pharmacies must have an active pharmacy license in the applicant’s home state. The Board may inspect a non-resident pharmacy if deemed necessary.

C.5 CLASS-B HOSPITAL PHARMACY

A Class B Hospital Pharmacy is defined as:

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

A Class B pharmacy can provide pharmacy services to the general public, including, to hospital staff and hospital outpatients. A separate Class A Community/Ambulatory pharmacy permit is not required. However, a specialized permit classification would be required for any specialty pharmacy services (e.g., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).

Hospital clinics/facilities eligible for a Class-B permit may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements (this list is not exhaustive). The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board’s jurisdiction. Applicants should consult with legal counsel to determine if a hospital clinic/facility is under “common control, management or ownership of the same hospital or hospital system.” The Board cannot provide legal advice.
Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area and pharmacy activity would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses.

20 CSR 2220-6.055 allows a pharmacist to perform authorized non-dispensing activities at a non-pharmacy location, such as medication therapy management/services, drug utilization review, patient consultation and prescription order entry/review (this list is not exhaustive). A Class-B pharmacy permit is not required for allowed non-dispensing activities unless technicians will be assisting at the non-pharmacy location. *Note: A pharmacy permit is not required if technicians are only assisting with vaccine administration; See C.16 for additional information*.

**Class-B Licensure for Missouri Hospitals**

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

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

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

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

**Authorized Class-B Activities**
Section 338.220, RSMo, grants two specific allowances to Class B Hospital pharmacies:

1) Class B Hospital pharmacies may dispense medication by prescription or by “medication order”;
and

2) Class B Hospital pharmacies may distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

Dispensing by Prescription/Medication Order

Section 338.220 authorizes Class-B pharmacies to dispense medication pursuant to a patient-specific prescription or a patient-specific medication order. Prescriptions must comply with all state and federal requirements, including the required two-line format for Missouri prescribers.

A “medication order” is defined as an order for a legend drug or device that is:

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

2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized designee at a hospital or a “hospital clinic or facility” that is under the “common control, management or ownership of the same hospital or hospital system.” Section 338.165.1, RSMo

Medication orders do not have to be in two-line format, however, orders must comply with all state/federal controlled substance requirements. Missouri law is silent on a pharmacist’s authority to perform generic or biosimilar substitution on a medication order. Please consult an attorney for guidance.

Significantly, medication orders can only be used to dispense medication that will be distributed or administered at a hospital or at a qualifying “hospital clinic or facility.” A qualifying hospital clinic or facility could include offsite physician clinics, urgent-care centers, long-term care facilities, infusion clinics, physical therapy units or other healthcare facilities, provided the clinic or facility is under common control, management or ownership of the same hospital or hospital system.

The Board has been asked if a medication order may be used to dispense a self-contained medication therapy course that will be initially administered onsite but later sent home/transferred with a patient to complete/continue administration (e.g., intrathecal and 5-FU pumps). The Board has determined that a medication order may be used in these instances provided administration is initiated onsite at the hospital or a qualifying hospital clinic or facility but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.

Labeling

Labeling must comply with § 338.059, RSMo (see E. 4 Labeling). The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite
Licensees can only distribute non-patient specific compounded preparations medication if they are registered with the FDA as a manufacturer or a section 503(b) drug outsourcer under the federal Drug Quality and Security Act. Licensees should consult with legal counsel to ensure compliance with state and federal law.

Record-Keeping
Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. The Board has determined that Class-B pharmacies may maintain dispensing, distribution and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the records must be readily retrievable on inspection or if requested by the Board. Note: Controlled substance records must still be separately maintained/retrievable as required by state/federal law.
C.6 CLASS-J SHARED SERVICES

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

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

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

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

Each pharmacy participating in a shared service arrangement must have a Class-J permit. Additionally, both pharmacies must maintain a policy and procedure manual that describes/includes:

1) Procedures for identifying the duties of each pharmacy, including, authorized Class-J duties;
2) A mechanism for tracking the prescription/medication order during each step in the process;
3) Security provisions for protecting the confidentiality and integrity of patient information;
4) Procedures for ensuring age and appropriate prescription delivery in compliance with 20 CSR 2220-2.013, and
5) A designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190.

Prescriptions or medication orders must be labelled in accordance with state and federal law. For purposes of § 338.059, either the name and address of the pharmacy responsible for offering patient counseling may be listed on the label or the pharmacy responsible for dispensing to the patient may be listed on the label as designated by the pharmacies by contract.

Quality Assurance Program:
Class-J pharmacies must maintain a quality assurance program that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and resolve identified problems. Proof/documentiation of your quality assurance program will be requested during an inspection.

Transferring prescription information between Class-J pharmacies that share a real-time, on-line database are not considered “prescription transfers” under 20 CSR 2220-2.120. However, other controlled substance laws may apply.

C.7 Class-L Veterinary Pharmacy
Pharmacies with a Class-A or Class-B pharmacy permit may dispense or provide legend drugs for both animal and human use. In 2012, Missouri law was amended to establish a Class-L Veterinary pharmacy permit for entities only dispensing or providing legend drugs for animal use. Class-L pharmacies must comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board. However, rule 20 CSR 2220-2.675 establishes additional exemptions/allowances to accommodate Class-L dispensing.

Specifically, 20 CSR 2220-2.675 establishes the following exemptions/allowances for Class-L pharmacies:

- Class-L pharmacies may operate without a pharmacist physically present on-site, provided the PIC reviews the activities and records of the pharmacy’s operations on a monthly basis. This exemption does not apply if controlled substances are stored, dispensed or provided (See Pharmacy Supervision below);
- Non-controlled legend drugs can be dispensed/filled without a pharmacist present, provided the PIC reviews the pharmacy’s dispensing records on a monthly basis (see Dispensing Without a Pharmacist below);
- In lieu of a separate and distinct pharmacy area, Class-L services can be provided in the same space or area as other business operations/activities provided there is a defined area for storing legend drugs. The defined drug area must be clean and sanitary and legend drugs must be properly identified at all times. Additionally, medication must be stored within the appropriate temperature requirements as provided by the manufacturer or the latest edition of USP; and
- Class-L pharmacies must have appropriate sewage disposal and a hot and cold water supply. The required water supply may be located outside of the pharmacy area provided the water supply is accessible to pharmacy staff (This exemption does not apply if compounding is performed. Class-L pharmacies engaged in non-sterile or sterile compounding must have a hot and cold water supply within the pharmacy). [20 CSR 2220-2.675(4)(F)]

Once again, the above exemptions/allowances only apply to Class-L pharmacies providing legend drugs for animal use. An additional pharmacy permit would be required to dispense any other legend drug or device.

Although Class-A and Class-B pharmacies may provide legend drugs for animal use under their Class-A/Class-B permit, a Class-L permit would need to be added to allow a Class-A/Class-B permit to use the above exemptions/allowances.

**Prescription Requirements:** To be valid for dispensing, prescriptions for animal use must comply with § 338.056, RSMo, and § 338.196. Additionally, prescriptions must include:

1) The client’s/owner’s name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;
2) The prescriber’s name, if an oral prescription, or signature, if a written prescription;
3) Name, strength, and dosage form of drug and directions for use;
4) The number of refills, when applicable;
5) The quantity prescribed in weight, volume, or number of units;
6) The address of the prescriber and the patient when the prescription is for a controlled substance;
7) Whether generic substitution has been authorized; and
8) The prescriber’s Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance. [20 CSR 2220-2.675(7)]

Controlled substance prescriptions must also comply with state/federal controlled substance laws. Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the Board (see Section H).

**Labeling:** Legend medication for animal use must be manually or electronically labeled in accordance with § 338.059, RSMo. Labels must also include:

1) The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and
2) 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). [20 CSR 2220-2.675(9)]

**Pharmacy Supervision:** 20 CSR 2220-2.675(6) provides a Class-L pharmacy may operate without a pharmacist on-site, provided the PIC reviews the pharmacy’s records and activities on a monthly basis to ensure compliance with state and federal law. The date of the required monthly PIC review must be documented in the pharmacy’s records.

This exemption does not apply if the pharmacy sells, dispenses or otherwise provides controlled substances. A pharmacist must be present during pharmacy operations if controlled substances are provided or dispensed. Additionally, a pharmacist must be present whenever compounding is performed (sterile or non-sterile).

**Dispensing without A Pharmacist:** Class-L pharmacies may accept, fill, enter or dispense non-controlled legend drugs for animal use in the absence of a pharmacist. The pharmacy must have specific policies and procedures for accepting or filling prescriptions/veterinarian orders without a pharmacist as well as policies and procedures for reporting and handling dispensing errors. All dispensing errors must be reported to the PIC within twenty-four (24) hours.

This exemption does not apply to controlled substances. All controlled substances must be verified by a pharmacist before dispensing.

Patient/client counseling must be offered each time medication is dispensed/provided by a Class-L pharmacy, as required by 20 CSR 2220-2.190. If the pharmacist is not on-site, a written offer to counsel with a toll-free telephone number for contacting a pharmacist must be provided.

The PIC must review the prescription records for all legend medication provided without a pharmacist present on a monthly basis. The PIC should be designated as the dispensing pharmacist for these prescriptions/orders unless verified by another pharmacist. The date of the required monthly PIC review must be documented in the pharmacy’s requirements.

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**Compounding:** Compounding of legend drugs may only be performed when a pharmacist is on site. Compounding must comply with 20 CSR 2220-2.200 (non-sterile compounding) and 20 CSR 2220-2.400 (sterile compounding).

**Controlled Substances:** Class-L pharmacies must comply with all state/federal controlled substance laws, including, all security and prescription/order requirements. A pharmacist must be present and onsite during pharmacy operations if controlled substances are sold or provided.

**Policies and Procedures:** Class-L pharmacies are required to maintain a policy and procedure manual that includes policies/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. Offering patient/client counseling;
6. If applicable, procedures for dispensing or providing prescriptions in a pharmacist’s absence;
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, including, provisions for notifying the PIC of dispensing errors within the required twenty-four (24) hours.

The policy and procedure manual must be reviewed annually by the PIC and must be available on inspection or at the request of the Board.

**C.8 Class M Specialty (Bleeding Disorder)**

A Class-M pharmacy permit is required for pharmacies providing or offering to provide blood-clotting factor or products to patients with bleeding disorders. As detailed below, § 338.400, RSMo, and rule 20 CSR 2220-6.100 contain additional compliance requirements for:

- Class-M pharmacies dispensing blood-clotting factor concentrates; and
- Class-M pharmacies dispensing blood clotting products to “established patients” or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients

**Dispensing Blood-Clotting Factor Concentrates**

Class-M pharmacies dispensing blood-clotting factor concentrates to new or existing patients are required to comply with the following:

1) Barring extenuating circumstances, blood clotting factor concentrates must be dispensed within plus or minus ten percent (+/- 10%) of prescribed assays, or as otherwise authorized or directed by the prescriber. [20 CSR 2220-6.100(2)(E)].

2) *Prescription Changes/Substitutions:* As with all medication, prescriptions for blood-clotting factor concentrates must be dispensed as written or as authorized by the prescriber. If the prescriber authorizes the pharmacy to change or substitute the blood-clotting factor concentrate originally prescribed, the patient/patient’s designee must be notified and counseled regarding the
change or substitution prior to dispensing via the patient’s identified preferred contact method (see below). Counseling is mandatory unless refused by the patient/designee. [20 CSR 2220-6.100(2)(A)].

3) **Automatic Refills:** Unless previously authorized by the patient or the patient’s designee, the pharmacy must contact the patient for authorization to dispense prior to shipping a refill of any blood-clotting product. Authorization may be given verbally or in writing. The authorization date must be documented in the pharmacy’s prescription records. The Board also recommends documenting the method/manner of authorization (e.g., written or verbal). [20 CSR 2220-6.100(2)(D)].

4) **Delivery Requirements:** If requested, blood-clotting factor concentrates must be shipped and delivered to the patient within two (2) business days for established patients in non-emergency situations and three (3) business days for new patients. Non-emergencies 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. [20 CSR 2220-6.100(2)(B)].

5) **Pharmacy Contact:** A toll free number for the pharmacy must be provided to patients to report problems with a delivery or product. The toll free number must be provided each time a prescription is dispensed (both new and refill). [20 CSR 2220-6.100(2)(C)].

6) **Preferred Contact Method:** The patient or the patient’s designee must be asked 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. [20 CSR 2220-6.100(2)(C)]. The preferred contact method must be documented in the patient’s prescription records.

7) **Recall/Withdrawal Notifications:** Licensees must notify the patient and the prescriber within twenty-four (24) hours after notification from the manufacturer or from any state/federal entity of a recall or withdrawal of any concentrate or ancillary infusion equipment/supplies. Notification is only required if the manufacturer or state/federal entity requires or recommends patient notification. The pharmacy must contact the prescriber to obtain a new prescription if necessary to dispense a substitute or alternative product. [20 CSR 2220-6.100(2)(F)1.].

If attempts to contact the patient via the preferred contact method are unsuccessful, notification must be mailed to the patient/patient’s designee within the required twenty-four (24) hours or the next business day. The time, date, and method(s) of notification must be documented in the pharmacy’s records and maintained for two (2) years from the date of recall or withdrawal. [20 CSR 2220-6.100(2)(F)].

Examples of currently known blood-clotting factor concentrates include, but may not be limited to:

- Recombinant Factor VII & Recombinant-activated Factor VIIa;
- Recombinant Factor VIII & plasma-derived Factor VIII;
- Recombinant Factor IX & plasma-derived Factor IX;
- von Willebrand factor products;
• Bypass products for patients with inhibitors;
• Prothrombin complex concentrates; and
• Activated prothrombin complex concentrates.

As currently approved by the FDA blood-clotting factor concentrates do not include:
• Aminocaproic Acid;
• Desmopressin Acetate;
• Warfarin; and
• Heparin

Dispensing Blood-Clotting Products
In addition the above, 20 CSR 2220-6.100(3) establishes requirements for Class-M pharmacies dispensing blood clotting products to “established patients” or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients. Section 338.400(4), RSMo, defines a “blood-clotting product” as:

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

Except as otherwise provided by § 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. [20 CSR 2220-6.100(1)(B)].

An “established patient” is 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. [20 CSR 2220-6.100(1)(C)]. “Bleeding disorder” is defined as:

A medical condition characterized by a deficiency or absence of one (1) 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. [20 CSR 2220-6.100(1)(A)]

A “bleeding disorder” does not include bleeding conditions secondary to another medical condition or diagnosis, except for acquired hemophilia. [20 CSR 2220-6.100(1)(A)].

Class-M pharmacies that meet the above definitions have to comply with the following:
1) **Board Notification:** The pharmacy must notify the Board annually if the pharmacy intends on providing legend blood-clotting products to bleeding disorder patients. Notification must be made on or before January 31st of each year and should be submitted online at: [http://pr.mo.gov/pharmacists-onlineservices.asp](http://pr.mo.gov/pharmacists-onlineservices.asp) [20 CSR 2220-6.100(3)(A)].

2) **Pharmacist Availability:** A pharmacist must 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 shipping/delivery time frames referenced below. [20 CSR 2220-6.100(3)(C)].

3) **Supply Requirements:** The pharmacy must identify, or make arrangements with, a supplier(s) who can provide all brands, assays and vial sizes of FDA approved blood-clotting products, including both, plasma and recombinant products. A list of identified suppliers must be maintained at the pharmacy and available during inspection. Products do not have to be pre-purchased. Instead, the pharmacy must have an identified supplier if a product is needed. [20 CSR 2220-6.100(3)(B)].

4) **Ancillary Supplies:** Ancillary equipment and supplies required to infuse blood-clotting products intravenously must be available for purchase, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs. Items must be restocked in a reasonable amount of time but in no event later than seven (7) calendar days. [20 CSR 2220-6.100(3)(H)].

5) **Shipping/Delivery Requirements:** If requested by an established patient, the pharmacy must provide for the shipment and delivery of blood-clotting products to the patient within two (2) business days after receiving a prescription or refill request. For new patients, shipment/delivery must be made within three (3) business days. In the event of an emergency, established patients must be provided access to blood-clotting products within twelve (12) hours after notification from the prescriber that an emergency supply is needed. Emergency requests must be documented in the pharmacy’s records.

If the pharmacy is waiting for action from a third-party payor prior to shipping/delivery (e.g. authorization, certification, etc.), the patient must be notified that the prescription is ready and explain any alternate payment options. Notification must be made as soon as reasonably practicable but in no event later than the required delivery timeframe. Pharmacies may delay shipping/delivery until payment is confirmed.

6) **Pharmacist Training/Continuing Education:** Pharmacists engaged in dispensing or filling blood-clotting factor concentrates for established patients or who provide patient counseling on blood clotting factor concentrates to bleeding disorder patients must have sufficient knowledge, experience and training to perform the duties assigned. Additionally, pharmacists engaged in counseling bleeding disorder patients must complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment/therapy or blood-clotting disorders or diseases each biennial renewal period. [20 CSR 2220-6.100(3)(D)]. The required CE hours can be used to meet the biennial pharmacist CE requirements. **Note:** The additional CE is only required for pharmacists engaged in dispensing or filling blood-clotting factor concentrates for “established patients” (see...
7) **Hazardous Waste:** Hazardous waste disposal containers must be provided or available for purchase at the pharmacy (e.g., Sharp containers). [20 CSR 2220-6.100(3)(G)].

8) **National Register:** The pharmacy must register with the National Patient Notification System, or its successor, to receive recall notifications for all products included in the National Patient Notification System. Registration is free and may be completed online at [http://www.patientnotificationsystem.org/](http://www.patientnotificationsystem.org/). Contact information must be kept current and accurate. [20 CSR 2220-6.100(3)(K)].

9) **Nursing Services:** Contact information must be available for a nurse/nursing service with experience in providing infusion related nursing services or nursing services for bleeding disorder patients, if the nursing services are not provided by the pharmacy. [20 CSR 2220-6.100(3)(I)].

10) **Insurance Information:** If requested, the pharmacy must explain any known insurance copayments, deductibles, coinsurance payments or lifetime maximum insurance payment limits. [20 CSR 2220-6.100(3)(J)]. The Board recognizes that licensees may have limited access to or knowledge of benefit information. 20 CSR 2220-6.100(3)(J) provides the pharmacy may rely on information supplied by the patient’s insurer.

11) **Policy & Procedure Manual:** The pharmacy must establish a written policy & procedure manual to ensure compliance with § 338.400 and 20 CSR 2220-6.100. Required policy & procedures include policies/procedures for: processing prescriptions, partial fills, providing/documenting recall notifications, emergency dispensing and cold chain management/packaging (This list is not exclusive; See 20 CSR 2220-6.100(4) for all policy and procedure requirements). Policies and procedures must be reviewed annually. Documentation of the annual review must be maintained in the pharmacy’s records. [20 CSR 2220-6.100(4)].

### C.9 CHANGE OF OWNERSHIP

Pharmacy permits are issued for a named permit holder and are not transferable. Accordingly, a permit becomes void on the effective date of an ownership change and a new pharmacy permit is required for the new owners. [20 CSR 2220-2.020(3)]. Once a completed Change of Ownership Permit Application has been filed, the Board may issue a temporary pharmacy permit to allow the new ownership to continue operating until a new permit is issued.

- **Sole Proprietors:** A pharmacy owned by a sole proprietor will be deemed to have changed ownership if: 1) the proprietor enters into a partnership with another individual or business entity, or 2) the proprietor dies. [20 CSR 2220-2.020(3)].

- **Corporations, LLCs, LLPs:** A new pharmacy permit is required if a corporation, limited liability partnership (“LLP”), or limited liability company (“LLC”) begins or transfers ownership of a pharmacy. A new permit is required regardless of the relationship between the previous and subsequent owners.

A Change of Ownership application is **not** required if:
• The pharmacy is owned by a corporation and the owners of the stock change. However, individuals/entities must notify the Board in writing within thirty (30) days of acquiring more than twenty-five percent (25%) of a pharmacy’s ownership, or;
• The members or partners of a LLP or LLC change, as long as the partnership or company is not dissolved by the change. Partner/member changes must be reported to the Board in writing within ten (10) days after the change. [20 CSR 2220-2.020(3)].

A new or amended controlled substance registration may also be required.

C.10 CHANGE OF LOCATION/REMODELING

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

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

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

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

C.11 TERMINATION OF BUSINESS

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

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

A complete inventory of all controlled substances transferred or disposed of must be completed on the termination date. [20 CSR 2220-2.015(2)(A)]. If controlled substances are transferred to another pharmacy, the inventory will serve as the final inventory for the terminating pharmacy and the initial inventory for the receiving entity. A copy of the inventory must be included in the records of each permit.
holder involved in the transfer. Controlled substances must be transferred via invoice or, if applicable, a DEA-222 form or CSOS.

**Records:** The closing pharmacy must designate a secure location where pharmacy records will be kept after the pharmacy is closed. The Board recommends informing patients of where/how to locate prescription records in the future. Records transferred to an unlicensed location must be retrievable within seven (7) working days of a Board request. [20 CSR 2220-2.015(1)(C)].
Pharmacies must be operated in a manner that will protect the public health and ensure the safe provision of pharmacy services. Pharmacy compliance requirements will differ based on the pharmacy’s permit classification and activities. This section summarizes general operational standards applicable to all pharmacies. Licensees should thoroughly review Chapter 338 and the rules of the Board to ensure compliance.

D.1 LICENSE POSTING

The pharmacy’s permit and the licenses/registrations of all pharmacists, intern pharmacists and technicians working in the pharmacy must be conspicuously displayed in the pharmacy area. [20 CSR 2220-2.010(1)(K)]. Pharmacist licenses must be accompanied by a 2”x 2” photo. In lieu of posting, pharmacists working at more than one pharmacy must have proof of licensure in their possession (e.g., license wallet card, online license verification). [20 CSR 2220-2.010(1)(L)].

D.2 REQUIRED EQUIPMENT/REFRIGERATION

Pharmacies must be equipped with proper equipment and reference manuals for the pharmacy services provided. [20 CSR 2220-2.010(1)(C) – (D)]. The Board does not approve specific brands or products. However, the following minimum equipment is required:

- Any basic equipment recognized by the latest edition of the United States Pharmacopeia (USP), the United States Pharmacopeia/Drug Information (USP/DI) or Remington’s: The Science and Practice of Pharmacy;
- A suitable machine/device for numbering prescriptions or assigning a unique identifier;
- Printing equipment for prescription labels;
- The current or latest edition of a reference manual(s) which includes all FDA approved drugs and information on pharmacology, dosages and clinical effects of drugs, and patient information; and
- A current edition of statutes and rules governing the pharmacy’s practice.

Reference materials can be maintained electronically or in print. However, the materials must be accessible to pharmacy staff and immediately retrievable during an inspection.

Drug Storage Areas: Pharmacies must have adequate refrigeration and sufficient storage space for drug inventory. Drug storage areas must be thermostatically controlled within the temperature requirement(s) provided by the manufacturer or USP. [20 CSR 2220-2.010(1)(G)]. To ensure compliance, drug storage areas should have a thermometer or other temperature monitoring device. Food and beverages for personal consumption must be stored separately from drugs and drug-related devices unless the food/beverage is unopened and in the sealed, original manufacturer packaging. Food/beverages for patient use, temperature control or compounding may be stored with drugs/drug-related devices provided sanitary conditions must be maintained at all times. [20 CSR 2220-2.010(1)(G)].

* Licensees should review package labeling as some products have special storage and temperature requirements and may not be stored in certain refrigeration/freezer units (e.g., dormitory style refrigerators).

D.3 PHARMacist-IN-CHARGE

All licensed pharmacies must designate a licensed pharmacist to serve as “pharmacist-in-charge” (PIC). [20 CSR 2220-2.010(1)(M)]. The PIC is personally responsible for supervising pharmacy activities and for ensuring full compliance with all state and federal drug law in conjunction with the permit holder.
Rule 20 CSR 2220-2.090 contains a detailed listing of PIC responsibilities/duties. Pharmacists should carefully review the rule prior to assuming accepting responsibilities. The Board also recommends that pharmacists review:

- The nature and volume of the pharmacy’s activities, and
- The pharmacy’s prior compliance history. This should include reviewing the Board’s previous inspection reports/compliance notices and any prior disciplinary orders. New PICs should make sure previous violations have been addressed and corrected.

A pharmacist may serve as PIC for more than one pharmacy. However, the PIC must be actively engaged in the operation of each pharmacy and may be held responsible for compliance violations even when the PIC is not present.

In the event of a PIC change:

- The former PIC must immediately notify the Board when he/she stops serving as PIC. [20 CSR 2220-2.010(1)(M)]. The pharmacy may not continue operations until a new PIC has been designated.
- The new PIC may begin serving immediately after designation. However, the permit holder must promptly submit a fully completed Pharmacist-In-Charge Change Application to officially complete the change. [20 CSR 2220-2.010(1)(M)]. Applications not received in a timely fashion may result in the PIC designation being voided or other disciplinary review/action. The mailing date should be documented and maintained in the pharmacy’s records.
- The permit holder and new PIC must complete a controlled substance inventory at the time of the PIC change that includes all Schedule II through V controlled substances, including, Schedule V pseudoephedrine containing over-the-counter products. Documentation of the inventory must be maintained in the pharmacy’s records. To ensure accuracy, the Board recommends that the former and new PIC jointly conduct the inventory.

Agreeing to serve as PIC is a serious responsibility. Once again, PICs can be held personally responsible for compliance violations. Pharmacists should not agree to serve as PIC if they cannot adequately supervise and monitor the pharmacy. The Board’s website contains additional resources for PICs, including, a Pharmacy Self-Assessment Guide that can be used to assess the pharmacy’s compliance status before an inspection.

Extended Leave: If a PIC will be on extended leave (e.g., vacation, maternity leave), the PIC and permit holder should review the pharmacy’s operations to determine if a new PIC should be named. If a new PIC is named, an official Pharmacist-In-Charge Change application must be filed. A second Pharmacist-In-Charge Change application must be filed when the previous PIC resumes PIC duties. Both PIC changes would require a separate controlled substance inventory.

Under § 338.210.5, the PIC is responsible for pharmacy compliance even if pharmacy policies/procedures are set corporately or by the pharmacy’s owners. Compliance violations could result in disciplinary action against the PIC’s pharmacist license as well as the pharmacy’s permit.

D.4 PHARMACY SUPERVISION

A pharmacist must be present and on duty at all times when the pharmacy is in operation or when prescriptions are being compounded, prepared, distributed or dispensed. Pharmacy technicians may assist in any area of pharmacy practice. However, technicians may not work independently and must be under the
“direct supervision and responsibility” of a Missouri-licensed pharmacist at all times. [20 CSR 2220-2.700].

When no pharmacist is on duty, a sign must be posted on the prescription counter and on all entrance doors informing the public that “no pharmacist is on duty.” Sign lettering may be no smaller than two inches (2”) in height. [20 CSR 2220-2.010(1)(A)]. The “no pharmacist on duty sign” does not have to be posted if the pharmacist is in the pharmacy building but briefly absent from the pharmacy area (e.g., restroom breaks).

Remote supervision of pharmacy technicians is not allowed in Missouri.

D.5 POLICIES AND PROCEDURES

Effective policies and procedures promote consistency and prevent compliance violations when shared with and practiced by pharmacy staff. Generally, Missouri law requires the following pharmacy policies and procedures:

<table>
<thead>
<tr>
<th>Policy/Procedure Type</th>
<th>Regulation</th>
<th>Annual Review Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>20 CSR 2220-2.090 (2)(P)</td>
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<tr>
<td>Class C: Long Term Care</td>
<td>20 CSR 2220-2.145</td>
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<tr>
<td>Class E: Radiopharmaceutical</td>
<td>20 CSR 2220-2.500</td>
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<tr>
<td>Class F: Renal Dialysis</td>
<td>20 CSR 2220-2.600</td>
<td></td>
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<tr>
<td>Class H: Sterile Products Compounding</td>
<td>20 CSR 2220-2.200</td>
<td>√</td>
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<tr>
<td>Class I: Consultant</td>
<td>20 CSR 2220-2.010 (10)</td>
<td>√</td>
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<tr>
<td>Class J: Shared Service</td>
<td>20 CSR 2220-2.650</td>
<td></td>
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<tr>
<td>Class L: Veterinary</td>
<td>20 CSR 2220-2.675</td>
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</tr>
<tr>
<td>Class M: Specialty (Bleeding Disorder)</td>
<td>20 CSR 2220-6.100</td>
<td>√</td>
</tr>
<tr>
<td>Classes N &amp; O: Automated Dispensing System</td>
<td>20 CSR 2220-2.900</td>
<td></td>
</tr>
<tr>
<td>Administration by Medical Prescription Order</td>
<td>20 CSR 2220-6.040</td>
<td>√</td>
</tr>
<tr>
<td>Automated Filling Systems</td>
<td>20 CSR 2220-2.950</td>
<td>√</td>
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<tr>
<td>Drug Take Back</td>
<td>20 CSR 2220-2.095(3)</td>
<td>√</td>
</tr>
<tr>
<td>Electronic Recordkeeping Systems</td>
<td>20 CSR 2220-2.083</td>
<td>√</td>
</tr>
<tr>
<td>Prescription Deliveries</td>
<td>20 CSR 2220-2.013(1)</td>
<td></td>
</tr>
<tr>
<td>Technician Duties</td>
<td>20 CSR 2220-2.090(2)(CC)</td>
<td></td>
</tr>
</tbody>
</table>

Note: Additional policies and procedures may be required by other state/federal law (e.g., DEA, BNDD).

Policies/procedures should be reviewed on a regular basis and updated as needed. Relevant changes should be shared and discussed with pharmacy staff to ensure compliance. Policies and procedures can be maintained electronically but must be readily retrievable during an inspection.

D.6 SECURITY

Pharmacies must maintain adequate security to deter drug theft/diversion. [20 CSR 2220-2.010(1)(H)]. Pharmacies located in facilities that have public access after the pharmacy’s normal hours of operation must also have sufficient alarm systems or locking mechanisms that are able to detect and prevent unauthorized access into the pharmacy (e.g., access via the ceiling or above gates/doors). Licensees should consider counter heights, wall/ceiling barriers and ease of public access when assessing the pharmacy’s security. The Board has received multiple reports of medication being stolen by customers who were able to reach into will-call bins or over prescription counters. Note: Licensees must also comply with all controlled substance security requirements.
Additional diversion prevention tips and resources are available on the Board’s website.

✓ Resources/videos on preventing or handling pharmacy robberies are available at [http://www.rxpatrol.com/](http://www.rxpatrol.com/). This website is provided for informational purposes only and is not sponsored or endorsed by the Board.

**D.7 OFFSITE WAREHOUSE/STORAGE SITES**

Any site/facility used to store medication or confidential pharmacy records offsite at an address or premises that is separate from the main pharmacy must be registered with the Board. [20 CSR 2220-2.010(1)(I), (J)]. An online Warehouse/Storage Site Notification Form is available on the Board’s website.

Off-site record storage locations must meet the following requirements:

- Adequate security must be maintained to protect confidentiality and prevent unauthorized access.
- At a minimum, the off-site location must be equipped with an alarm system;
- No record less than two years old may be stored off site;
- Security breaches must be reported to the Board within fifteen (15) days; and
- All records stored off site must be made available for inspection within two business days, if requested.

Pharmacies may share storage space if each pharmacy’s records and/or drug inventory can be individually identified and are securely stored to prevent unauthorized access. **Note:** Offsite storage would include storing records at another pharmacy and would require Board notification.

**D.8 STAFFING RATIOS**

Missouri law does not mandate staffing ratios (e.g., pharmacist-to-technician). However, the Board is concerned about the quality of services if staffing levels are inadequate for appropriate oversight and patient care. Licensees are strongly cautioned to maintain appropriate staffing levels to ensure public safety.

**D.9 NON-DISPENSING ACTIVITIES**

Generally, the practice of pharmacy may only be performed on the premises of a Missouri-licensed pharmacy. However, [20 CSR 2220-6.055](http://www.rxpatrol.com/) allows a Missouri-licensed pharmacist to perform the following non-dispensing activities outside of a licensed pharmacy:

1) Patient counseling/education  
2) Obtaining patient history/information  
3) Reviewing patient records/medical histories  
4) Patient assessment/evaluation, as authorized by Missouri law  
5) Billing and insurance claim submissions/review  
6) Drug utilization review  
7) Assessing payor eligibility/coverage  
8) Pharmacy compliance audits/evaluations  
9) Administering drugs, vaccines, or biologicals, as authorized by law and the rules of the Board  
10) Peer review/peer consultations  
11) Reviewing, selecting, and developing formularies or plan/practice guidelines  
12) Reviewing compliance with benefit guidelines  
13) Managing inventory, including purchasing and ordering  
14) Managing/reviewing information systems  
15) Patient medication review  
16) Consulting with other health care professionals  
17) Patient referrals  
18) Medication therapy management  
19) Prescription order entry/review, provided that a pharmacist may only accept a prescription on the premises of a Missouri licensed pharmacy
Pharmacists operating under 20 CSR 2220-6.055 are prohibited from meeting with patients in the pharmacist’s residence or living quarters.

The Board is frequently asked if a pharmacist in another state can be used to perform DUR or prescription order review for a Missouri licensed pharmacy. A pharmacist may perform non-dispensing activities at a facility located outside of Missouri for, or on behalf of, a Missouri pharmacy if:
- The individual is a Missouri licensed pharmacist, or
- The facility is licensed as a Missouri pharmacy and is operating under a Class J Shared Services arrangement.

✔ A pharmacy permit would be required if a pharmacy technician will be assisting at a non-pharmacy location with non-dispensing activities other than immunization.

### D.10 PHARMACY NOTIFICATIONS

Pharmacies are required to provide the following notifications to the Board (*this chart does not include controlled substance reporting requirements*):

<table>
<thead>
<tr>
<th>WHAT NEEDS TO BE REPORTED</th>
<th>WHEN?</th>
<th>STATUTE/RULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breach of security (Bd. registered offsite warehouse/storage facility)</td>
<td>Within fifteen (15) days after breach</td>
<td>20 CSR 2220-2.010(1)(I), (J)</td>
</tr>
<tr>
<td>Breach of security (Class-I Consultant pharmacy electronic data processing system)</td>
<td>Within seven (7) days of the breach of confidentiality</td>
<td>20 CSR 2220-2.010(10)(C)</td>
</tr>
<tr>
<td>Change of Classification</td>
<td>Prior to performing new classification activities</td>
<td>§ 338.220</td>
</tr>
<tr>
<td>Change of Location</td>
<td>Prior to operating at new location</td>
<td>20 CSR 2220-2.020(4)</td>
</tr>
<tr>
<td>Change of Ownership</td>
<td>Prior to operating under new ownership. <em>Note: Individuals/Entities acquiring more than 25% of a pharmacy’s ownership must notify the Bd. within 30 days</em></td>
<td>20 CSR 2220-2.020(1)/20 CSR 2220-2.020(3)(B)</td>
</tr>
<tr>
<td>Change of Partners/Members (Pharmacy LLPs or LLCs)</td>
<td>Within ten (10) days after the partnership/membership change</td>
<td>20 CSR 2220-2.020(3)(C)</td>
</tr>
<tr>
<td>Final disciplinary action against a technician or a qualifying voluntary resignation <em>(See A.4)</em></td>
<td>Within fifteen (15) days after action/resignation</td>
<td>§ 338.013</td>
</tr>
<tr>
<td>Final adverse action, license surrender or federal exclusion involving or against the pharmacy <em>(See A.4)</em></td>
<td>Within seven (7) days after action/exclusion</td>
<td>§ 338.075</td>
</tr>
<tr>
<td>Final disciplinary action against a pharmacist employed to provide health care services or a qualifying voluntary resignation <em>(See A.4)</em></td>
<td>Within fifteen (15) days after action/resignation</td>
<td>§ 383.133</td>
</tr>
<tr>
<td>Section</td>
<td>Requirement</td>
<td>Reference</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Intent to provide legend blood-clotting</td>
<td>On or before January 31st annually</td>
<td>20 CSR 2220-6.100(3)(A)</td>
</tr>
<tr>
<td>products to bleeding disorder patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Class-M Pharmacies)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Out of Business Notification</td>
<td>Within fifteen (15) days after terminating business</td>
<td>20 CSR 2220-2.015(1)</td>
</tr>
<tr>
<td>Pharmacy Remodeling</td>
<td>Remodeling affidavit &amp; project plans filed with Board within thirty (30) days before the change</td>
<td>20 CSR 2220-2.020(4)(A)</td>
</tr>
<tr>
<td>PIC Change</td>
<td>Promptly after new PIC is designated</td>
<td>20 CSR 2220-2.010(1)(M)</td>
</tr>
<tr>
<td>Recall of a compounded preparation deemed</td>
<td>Within three (3) business days after the recall. <strong>Prescriber notification also required</strong></td>
<td>20 CSR 2220-2.200(21), 20 CCSR 2220</td>
</tr>
<tr>
<td>to be misbranded, adulterated or sterile</td>
<td></td>
<td>2220-2.400(8)(C)</td>
</tr>
<tr>
<td>preparations deemed to be non-sterile or if</td>
<td></td>
<td></td>
</tr>
<tr>
<td>end-preparation testing results are out of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>specification.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STERILE COMPOUNDING:</td>
<td>Within seven (7) days of detection</td>
<td>20 CSR 2220-2.200(20)(B)</td>
</tr>
<tr>
<td>Detection of a highly pathogenic microorganism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>in any preparation or as the result of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>environmental monitoring/testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(regardless of CFU count)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theft/diversion of or from a collection</td>
<td>Within fourteen (14) days</td>
<td>20 CSR 2220-2.095(4)(F)</td>
</tr>
<tr>
<td>receptacle authorized by 20 CSR 2220-2.095 to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>collect used medication for destruction</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

✅ The Centers for Medicare & Medicaid Services (CMS) regulates all non-research laboratory testing on humans pursuant to the Clinical Laboratory Improvement Amendments (CLIA). CLIA regulates three categories of testing: moderate complexity testing, high complexity testing and CLIA waived testing that does not pose a significant risk of patient harm if the test is performed correctly. Missouri law does not address pharmacies or pharmacists performing CLIA testing, including, CLIA waived testing. Absent statutory direction, licensees performing authorized CLIA/CLIA waived testing should consult with legal counsel and review federal law to ensure compliance.
E.1 GENERAL REQUIREMENTS

Except as otherwise provided by state or federal law, licensees may only dispense medication pursuant to a “prescription” or “prescription drug order” from an authorized prescriber for a specific patient. [§ 338.095]. Class B pharmacies are also authorized to dispense by medication prescription order (See C.18). For purposes of Chapter 338, RSMo, and the Board’s rules, a “prescription” or “prescription drug order” is defined as:

A lawful order for medications or devices issued and signed by an authorized prescriber within the scope of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104, RSMo, to and for the ultimate user. The terms "prescription" and "drug order" do not include an order for medication requiring a prescription to be dispensed, which is provided for the immediate administration to the ultimate user or recipient. [§ 338.095].

Licensees may only change or modify an OTC product by prescription. Flavoring an OTC product by incorporating a flavoring agent requires a prescription.

E.2 AUTHORIZED PRESCRIBERS

To be valid for dispensing, a prescription must have been written by a prescriber that is licensed in the United States or a U.S. territory who is legally authorized to prescribe. [§ 338.095; 20 CSR 2220-2.020(11)]. Missouri law recognizes the following prescriptive authority:

<table>
<thead>
<tr>
<th>PRESCRIBER</th>
<th>AUTHORITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistant Physicians</td>
<td>Both controlled &amp; non-controlled prescriptive authority under a collaborative practice agreement with a Missouri licensed physician. See Section D.8.</td>
</tr>
<tr>
<td>Advanced Practice Registered Nurses</td>
<td>Both controlled &amp; non-controlled prescriptive authority if under a collaborative practice agreement with a Missouri licensed physician. See Section D.8.</td>
</tr>
<tr>
<td>Physicians, Dentists, Veterinarians, Podiatrists and Optometrists</td>
<td>May prescribe within their scope of practice.</td>
</tr>
<tr>
<td>Physician Assistants</td>
<td>Both controlled &amp; non-controlled prescriptive authority if under a supervisory agreement with a Missouri licensed physician. See Section D.8.</td>
</tr>
<tr>
<td>Out-of-State Prescribers</td>
<td>Prescriber must be legally authorized to prescribe in the prescriber’s licensing state/territory. The prescription may be filled even if similar prescriptive authority is not recognized in Missouri. (e.g., out-of-state chiropractors, pharmacists or psychologists with prescriptive authority).</td>
</tr>
<tr>
<td>Non-U.S. Prescribers</td>
<td>Prescriptions from a prescriber licensed in a foreign country or jurisdiction (e.g., Canada, Mexico) cannot be filled unless the practitioner is also licensed and legally authorized to prescribe in a U.S. state or territory. [§ 338.095; 20 CSR 2220-2.020(11)].</td>
</tr>
<tr>
<td>Military Prescribers</td>
<td>The Board does not have jurisdiction over pharmacy practice on military bases. Prescriptions from a member of the armed forces may be filled by a Missouri pharmacy if the prescription complies with all federal requirements.</td>
</tr>
</tbody>
</table>

Licensees are responsible for ensuring valid prescriptive authority and, if applicable, proper controlled substance authority. The DEA publishes a state listing of controlled substance prescribers.
at [http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf](http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf). The National Association of Boards of Pharmacy (NABP) also publishes a state-specific listing in its Annual Survey of Pharmacy Law that can be purchased at [https://nabp.pharmacy/](https://nabp.pharmacy/). Note: These resources are not maintained by the Board; the Board cannot guarantee their accuracy.

- **Self-Prescribing:** It is illegal for a physician to prescribe controlled substances for him/herself, unless it is a medical emergency (see § 195.070.5, RSMo). It is not illegal for a physician to prescribe non-controlled drugs for themselves, however, the practice is discouraged by the Board of Healing Arts.

- Physicians may prescribe controlled or non-controlled drugs for a family member, as long as the physician maintains the same records for family members as he/she would for any other patient and all other prescription requirements are met. Please consult the Board of Healing Arts for additional guidance.

### E.3 PRESCRIPTION FORMS

Pursuant to § 338.056, written prescriptions from a Missouri prescriber must be in two-line format with two signature lines on opposite ends of the bottom of the prescription. A prescriber note indicating “DAW,” “brand necessary” or “brand medically necessary” is insufficient. “Dispense as Written” must be printed under the signature line on the right and “Substitution Permitted” printed under the signature line on the left. [§ 338.056].

- **Faxed prescriptions must be in the required two-line format** (See D.10). Two-line format is not required for electronically transmitted prescriptions, however, the prescriber must indicate if generic substitution is authorized. (See also D.11).

Prescriptions from non-Missouri prescribers must be in the format approved in the state/territory where the practitioner is licensed.

**Security Paper:** Missouri law requires secure paper for prescriptions bearing an electronic signature and given to the patient. The paper must include security features that will detect or prevent the prescription from being copied or altered (e.g., watermark, microprint, heat detection/rub features). Prescriptions that are computer generated but physically signed by the prescriber do not need to be on security paper. [20 CSR 2220-2.085]. BND has confirmed that security paper is strongly recommended but not required for controlled substance prescriptions. Note: CMS may require tamper resistant paper for Medicaid reimbursement.

### E.4 GENERAL PRESCRIPTION REQUIREMENTS

To be valid for dispensing, a prescription must include:

- The date of prescribing;
- The name of the patients or, if an animal, species and owner’s name;
- The prescriber’s name, if an oral prescription, or written or electronic signature if a written, faxed, or an electronically transmitted prescription. Electronic signatures must comply with 20 CSR 2220-2.085;
- Name, strength and dosage of drug, device or poison prescribed and the directions for use;
- The number of refills, if applicable;
- The quantity prescribed in weight, volume, or number of units;
- An indication of whether generic substitution has been authorized by the prescriber, as required by § 338.056, RSMo, and;
• Any change or alteration made to the prescription based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or substitution authority. [See 20 CSR 2220-2.018].

New bullet

Controlled substance prescriptions must also include:

• The address of the prescriber and the patient
• The prescriber’s Drug Enforcement Administration (DEA) number
• For APRN, Assistant Physician and Physician Assistant prescriptions, the name, telephone number and address of both the physician and the prescribing APRN, Assistant Physician or Physician Assistant [20 CSR 2220-2.018; 20 CSR 2220-4.200(3)(G)7].

Changes in prescription orders may only be communicated by the prescriber or a duly authorized representative. Pending further DEA guidance, BNDD has provided the following additional guidance for schedule II controlled substances:

**Methods of changing C-II controlled substance prescriptions:**

1. A prescriber may provide a written change to the pharmacy that the pharmacy must attach to the original prescription. The written change must document the date and name of the person authorizing the change. The change may be mailed, emailed, or faxed.

2. The change may be communicated orally. The pharmacy shall record the date, changes, and person authorizing the changes on the front or back of the prescription.

<table>
<thead>
<tr>
<th>What may be changed/added on a controlled substance prescription with permission</th>
<th>What can never be changed/added</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date written</td>
<td>Patient’s name</td>
</tr>
<tr>
<td>Patient’s address <em>(complete physical address, not P.O. Box)</em></td>
<td>Drug name</td>
</tr>
<tr>
<td>Drug form</td>
<td>Prescriber’s name</td>
</tr>
<tr>
<td>Drug strength</td>
<td>Prescriber’s signature</td>
</tr>
<tr>
<td>Quantity to be dispensed</td>
<td></td>
</tr>
<tr>
<td>Prescriber’s address</td>
<td></td>
</tr>
<tr>
<td>Prescriber’s DEA number</td>
<td></td>
</tr>
<tr>
<td>Directions for use</td>
<td></td>
</tr>
<tr>
<td>Substitutions permitted</td>
<td></td>
</tr>
<tr>
<td>Refill information</td>
<td></td>
</tr>
<tr>
<td>Reasons for extended supplies for Schedule II prescriptions.</td>
<td></td>
</tr>
</tbody>
</table>

See BNDD’s Interim Schedule II Policy for full guidance.

**E.5 PATIENT-PRACTITIONER RELATIONSHIP**

Prescriptions must be based on a valid pre-existing patient-practitioner relationship. [20 CSR 2220-2.020(11)]. Additionally, the practitioner must have performed a valid medical examination as required by law. [20 CSR 2220-2.020(11)]. A prescription may not be filled if the pharmacist knows, or should reasonably know under the circumstances, that the prescription was based on an internet-based or telephone questionnaire. [20 CSR 2220-2.020(11)]. See Section D.12 for Telehealth/Telemedicine.

If the pharmacist knows or has reason to believe the patient is not under the prescriber’s care at the time the prescription is presented, the pharmacist is required to consult with the prescriber to determine if the prescriber intends for the medication to be dispensed. Confirmation should be documented in the prescription record.

[Table of Contents]
Retired, Deceased, Inactive or Disciplined Prescribers: Missouri law does not definitively address filling/refilling of prescriptions that were validly written before a prescriber passes away, stops practicing or is disciplined. Pharmacists should use their professional judgment in continuing to dispense refills and should advise patients to consult with another practitioner as soon as possible. Contact BNDD for guidance on dispensing controlled substances. See also Section E.17 for Emergency Dispensing options.

E.6 AUTHORIZED SIGNATURES

Non-Controlled Substances: Prescribers may sign a non-controlled prescription either manually or electronically. [§ 338.056]. Licensees may contact the prescriber to obtain an oral prescription if a signature is invalid.

- **Manual Signatures**: Prescribers may manually sign a prescription in the same manner used for signing a check or other legal document. Rubber-stamped signatures are not valid. The prescriber’s staff/agents may prepare the prescription. However, the prescriber must manually sign the prescription before it is issued.

- **Electronic Signatures**: A prescription may be electronically signed if: a) the prescription has been applied to secure paper that prevents/detects copying or alteration or b) the prescription is faxed to the pharmacy from the prescriber’s office or the prescriber’s authorized agent. [20 CSR 2220-2.085(2)(D), (E)]. To be valid, the electronic signature must be an exact electronic replica of the prescriber’s signature or consist of a confidential digital key code, number or other identifier that denotes prescriber authorization (e.g., "electronically prescribed by John Smith, MD") [20 CSR 2220-2.085(1)(D)]. [See also D.10- Faxed Prescriptions / D.11- Electronic Prescriptions].

Controlled Substances: Controlled substance prescriptions must comply with state/federal law. Generally, all paper and faxed controlled substance prescriptions must be manually signed by the prescriber. According to BNDD, digitally scanned signatures are not acceptable. With the exception of Schedule II controlled substances, licensees may obtain an oral prescription if the prescriber’s signature is invalid.

E.7 PRESCRIPTION LIMITS (PHYSICIANS)

The following Missouri prescription limits apply (controlled substance guidance provided by BNDD):

<table>
<thead>
<tr>
<th>Schedule II Controlled Substances</th>
<th>Schedule III-IV Controlled Substances</th>
<th>Schedule V Controlled Substances</th>
<th>Non-Controlleds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Validity</td>
<td>Six (6) Months</td>
<td>Six (6) Months</td>
<td>One (1) Year</td>
</tr>
<tr>
<td>Quantity Limits</td>
<td>30-Days/ 90-Days with documented medical reason</td>
<td>90-Days</td>
<td>90-Days</td>
</tr>
<tr>
<td>Refills</td>
<td>May not be refilled</td>
<td>Up to five (5) times within six (6) months</td>
<td>As prescribed</td>
</tr>
</tbody>
</table>

According to BNDD, out-of-state prescribers may prescribe controlled substances according to the authority of their home state (including APRNs, Assistant Physicians and Physician Assistants). If the patient is a Missouri patient, the controlled substance quantity limits listed above apply. If the patient is an out-of-state patient, the quantity limits of the prescriber’s home state apply. [See § 195.080]

E.8 MID-LEVEL PRACTITIONERS (APRNs, Assistant Physicians and Physician Assistants)

[Table of Contents]
Assistant physicians were granted prescribing authority in 2014. See § 334.036. Assistant physicians are recent medical school graduates who have received their medical degrees but have not yet entered a residency program. Assistant Physicians have the same prescribing authority as Physician Assistants.

APRNs, APs and PAs must have a current BNDD and DEA registration to prescribe controlled substances.
APRNs, APs & PAs may not purchase, stock, dispense, or administer controlled substances independently.

Prescriptions written by an APRN, AP or PA must include:
- The name, telephone number and address of the APRN, AP or PA;
- The supervising/collaborating physician’s name, telephone number and address;
- The APRN’s, AP’s or PA’s signature, and
- For controlled substances, the APRN’s, AP’s or PA’s DEA #. [§ 334.735.4, 20 CSR 2200-4.200(3)(G).7].

Non-controlled prescriptions are valid for one year and refills/quantity limits are as prescribed. For controlled substances, BNDD has issued the following guidance (the following would apply unless otherwise restricted in the governing protocol/supervisory agreement):

<table>
<thead>
<tr>
<th>Schedule II</th>
<th>Missouri Advanced Practice Registered Nurses</th>
<th>Missouri Assistant Physicians’ Assistants</th>
<th>Out-of-state Midlevel Practitioner</th>
</tr>
</thead>
</table>
|                              | • Hydrocodone products only- limited to a 5-day or 120-hour supply. *Includes single ingredient products. | • Hydrocodone products only- limited to a 5-day or 120-hour supply. * Includes single ingredient products. | Supply limit:  
• MO patient: 30-Day supply/90-Day supply with documented medical reason  
• Non-MO patient: As allowed in home state |
| Schedule III (Opiates)       | • Limited to a 5-day or 120-hour supply  
• Prescription valid for 6-months from date written.  
• No refills allowed*** | • Limited to a 5-day or 120-hour supply  
• Prescription valid for 6-months from date written  
• No refills allowed*** | Rx valid for 6-months from date written  
• Refills as allowed in home state.  
Supply limit:  
• MO patient: 90-Day supply  
• Non-MO patient: As allowed in home state. |
| Schedule III (Non-Opiates)   | • Full authority to prescribe  
• 90-Day quantity limits  
• Prescription valid for 6- | • Limited to a 5-day or 120-hour supply  
• Prescription valid for 6-months from date | Rx valid for 6-months from date written  
• Refills as allowed in |
### SECTION E: PRESCRIPTION REQUIREMENTS

<table>
<thead>
<tr>
<th>Schedule IV &amp; V</th>
<th>Family Members</th>
<th>Self-Prescribing</th>
</tr>
</thead>
</table>
| • Full authority to prescribe  
• 90-day supply limit for a single prescription  
• C-IV: Prescription valid for 6-months from date written  
• C-V: Prescription valid for 12-months from date written | No authority; Cannot prescribe controlled substances for family members as defined below | No authority; Cannot prescribe for themselves (all schedules) |
| • Full authority to prescribe  
• 90-day supply limit for a single prescription  
• C-IV: Prescription valid for 6-months from date written  
• C-V: Prescription valid for 12-months from date written | No authority; Cannot prescribe controlled substances for family members as defined below | No authority; Cannot prescribe for themselves (all schedules) |
| • C-IV prescription valid for 6-months from date written/C-V prescription valid for 12-months from date written  
• Refills as allowed in home state.  
| Supply limit:  
• MO patient: 90-Day supply  
• Non-MO patient: As allowed in home state.  

| MO patient: 90-Day supply  
• Non-MO patient: As allowed in home state.  

| As allowed by home state |

| Family Members | No authority; Cannot prescribe controlled substances for family members as defined below  
| Self-Prescribing | No authority; Cannot prescribe for themselves (all schedules) |

| As allowed by home state |

| Family Members | No authority; Cannot prescribe controlled substances for family members as defined below |

| Self-Prescribing | No authority; Cannot prescribe for themselves (all schedules) |

| As allowed by home state |

| Family Members | No authority; Cannot prescribe controlled substances for family members as defined below |

| Self-Prescribing | No authority; Cannot prescribe for themselves (all schedules) |

| As allowed by home state |

| Family Members | No authority; Cannot prescribe controlled substances for family members as defined below |

| Self-Prescribing | No authority; Cannot prescribe for themselves (all schedules) |

| As allowed by home state |

| Family Members | No authority; Cannot prescribe controlled substances for family members as defined below |

| Self-Prescribing | No authority; Cannot prescribe for themselves (all schedules) |

| As allowed by home state |

| Family Members | No authority; Cannot prescribe controlled substances for family members as defined below |

| Self-Prescribing | No authority; Cannot prescribe for themselves (all schedules) |

| As allowed by home state |

*** According to BNDD, a new prescription can be written for an additional 5-day supply, however, a new prescription and prescription number would have to be generated. BNDD would consider these new prescriptions and not refills. 

“Family” is defined in the state medical board’s rule as a spouse, parent, grandparent, great-grandparent, child, grandchild, great-grandchild, brother, sister, aunt, uncle, nephew, niece, mother-in-law, father-in-law, brother-in-law, sister-in-law, daughter-in-law or son-in-law (adopted and step members are included). [20 CSR 2150-5.100(3)(G)(10)]. 

#### E.9 TELEPHONE PRESCRIPTIONS

Pharmacists may accept a telephone prescription communicated by the prescriber or the prescriber’s duly authorized agent. [§ 338.095]. Telephone prescriptions must be promptly reduced to writing or electronically recorded in the pharmacy’s prescription records. Telephone prescriptions may be received by a pharmacist or by a technician/intern pharmacist acting under the pharmacist’s direct supervision. All prescription information required by 20 CSR 2220-2.018 must be recorded, including, substitution authorization.

#### E.10 FAXED PRESCRIPTIONS

Faxed prescriptions must be in the required two-line format and include all prescription information required by § 338.056 and 20 CSR 2220-2.018. A true faxed prescription is a full image of a physical prescription document that is faxed to the pharmacy. [20 CSR 2220-2.085(1)(B)]. In other words, the sender must insert a fully completed prescription document into the fax machine and fax the prescription. Fax prescriptions may only be sent by the prescriber or the prescriber’s authorized agent. Pharmacies are not allowed to fill prescriptions faxed by a patient.

[Table of Contents]
Pharmacists should use their professional judgment and take appropriate measures to verify/authenticate faxed prescriptions and their origin such as:

- Maintaining a practitioner fax number reference list or other electronic signature file;
- Verifying the telephone/fax number; or
- Orally verifying with the prescriber’s office that the prescription is correct as written and transmitted. [20 CSR 2220-2.085(2)(C)].

The original fax and any other information sent from the electronic source must be readily retrievable [20 CSR 2220-2.085(2)(A)]. Any alteration(s) to the prescription after dispensing must be authorized by the prescriber and documented in the prescription records along with the identity of the pharmacist responsible for the alteration [20 CSR 2220-2.085(2)(A)].

Non-Controlled Substances: Faxed non-controlled prescriptions may be manually signed or electronically signed as authorized by 20 CSR 2220-2.085. To be valid, the electronic signature must be an exact electronic replica of the prescriber’s signature or consist of a confidential digital key code, number or other identifier that denotes prescriber authorization (e.g., "electronically prescribed by John Smith, MD") [20 CSR 2220-2.085(1)(D)].

Controlled Substances: Faxed controlled substance prescriptions must be physically signed by the prescriber and must comply with all BNDD and DEA requirements. The DEA does not allow an electronically signed controlled substance prescription that is generated from a prescriber’s software to be converted to fax. See 20 CSR 2220-2.085 and Section D.11 for electronically transmitted prescription requirements.

**E.11 ELECTRONIC PRESCRIPTIONS**

Non-Controlled Substance Prescriptions: Prescriptions for non-controlled drugs may be transmitted electronically either as an exact visual image of the prescription (e.g., a fax) or in another electronic form (e.g., data transmission or scan). [20 CSR 2220-2.085(1)]. The prescription must be electronically transmitted by the prescriber or the prescriber’s authorized agent. Prescriptions electronically transmitted by the patient are not valid for dispensing.

✔️ *Prescriptions sent electronically from a prescriber’s computer software to the pharmacy’s fax machine are electronically transmitted prescriptions under the Board’s rules and are not considered “faxed prescriptions.”*

Controlled Substances: Electronic prescribing of controlled substances is allowed in Missouri if the pharmacy and prescriber use software that has been certified to meet DEA requirements. Prescribing must also comply with all DEA electronic prescribing requirements. (See BNDD’s rules- 19 CSR 30-1.048(9) and 19 CSR 30-1.062(4)). (See section D.11)

**E.12 TELEHEALTH/TELEMEDICINE**

Section 191.1145 allows a Missouri licensed healthcare provider to provide “telehealth” or “telemedicine” services which are defined as:

*The delivery of health care services by means of information and communication technologies which facilitate the assessment, diagnosis, consultation, treatment, education, care management, and self management of a patient’s health care while such patient is at the originating site and the health care provider is at the distant site. Telehealth or telemedicine shall also include the use of asynchronous store-and-forward technology.*
Significantly, telehealth/telemedicine does not include prescribing based solely on an internet or telephone questionnaire or prescribing based on a telephone examination without a valid prescriber-patient relationship. [§ 191.1146, § 334.108.(3) – (.4)]

A Missouri pharmacy may fill a prescription that is issued based on a valid “telehealth” or “telemedicine” exam. To be valid, a telemedicine prescription from a Missouri prescriber must meet the following requirements:

- The prescriber must be licensed to practice in Missouri, and
- The prescription must be based on a valid physician-patient relationship, and
- The prescription must comply with all other state/federal prescription requirements, including, 20 CSR 2220-2.018, § 338.056, RSMo (two-line format) and any applicable controlled substance laws, and
- The telemedicine services must be within the provider’s “scope of practice” and meet the applicable standard of care. [§ 191.1145, § 191.1146]

A telemedicine prescription CANNOT be filled if:

- The prescription was issued based solely on an internet request or an internet questionnaire, or
- No legitimate practitioner-patient relationship exists, or
- The prescription was based solely on a telephone evaluation without a previously established and ongoing prescriber-patient relationship exists. [§ 191.1146, § 334.108.(3) – (.4)]

Pharmacists should use their professional judgment when determining if a valid physician-patient relationship exists. Determining the applicable standard of care will depend on the health care provider’s licensing regulations and applicable medical standards. The Board cannot give additional guidance here. However, licensees should be attentive to prescriptions that appear to be outside of the prescriber’s scope of practice.

The Board is aware that prescribers frequently issue prescriptions after consulting with a patient over the phone. Once again, a prescription may be issued based on a telephone evaluation if “a previously ongoing physician-patient relationship exists” between the prescriber and the patient being treated. [Sec. 334.108.3]. This exception would allow prescribers to continue their current practice of consulting with patients over the phone if the provider and patient have a previously established, ongoing relationship.

Mid-Level Practitioners: Missouri’s telehealth/telemedicine provisions are applicable to prescriptions issued by “any licensed health care provider” which would include APRNs, assistant physicians and physician assistants acting within their licensed scope of practice. However, mid-level practitioners must comply with all applicable prescribing and collaborative practice requirements.

Controlled Substances: The Ryan Haight Act and federal controlled substance laws include specific requirements for telemedicine and controlled substances. Licensees should consult with legal counsel, the DEA and BNDD to ensure compliance with applicable federal law. The Board cannot give legal advice. The DEA has issued the following caution regarding controlled substances:

*The pharmacist who deliberately ignores a questionable prescription when there is a reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense which may result in the loss of one’s business or professional license.*

BNDD has also issued the following excerpted statement regarding telemedicine and controlled substance activities:

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The Missouri BNDD has reviewed the telemedicine statutes and discussed them with the Drug Enforcement Administration (DEA). The statutes provide definitions and make determinations on the delivery of telemedicine. As always, a state licensing board would make determinations regarding proper clinical care. For controlled substance prescribing and dispensing, the following issues are relevant:

- The controlled substance activity must be by an authorized and registered professional who is acting within their scope of professional practice and within the guidelines of Chapter 195, RSMo and its regulations.
- For Missouri practitioners who will be prescribing, the prescribers must have a professional Missouri license, a Missouri BNDD registration and a Missouri DEA registration. This registration must be at their primary practice location where they spend the most time.
- According to the DEA, pursuant to 21 USC 802(54), if the telemedicine is taking place across state lines, the prescriber must be licensed and also have DEA registrations in both states; the state they are prescribing from and also the state where the patient is. If the patient is an in-patient admitted to a hospital, the hospital may have one of their local practitioners issue the drug orders or the hospital may allow that out of state consulting physician to use the hospital’s DEA number pursuant to 21 CFR 1301.22(c).

Pharmacists play a vital role in preventing prescription fraud and abuse. Licensees are reminded of their corresponding responsibility and should exercise sound professional judgment when determining if a telehealth/telemedicine prescription is legitimate.

Out-of-State Prescribers: The Board understands the Missouri Board of Registration for the Healing Arts will be reviewing the applicability of Missouri’s telehealth/telemedicine provisions to out-of-state prescribers. In the interim, licensees are reminded that Board rule **20 CSR 2220-2.020(11)** provides:

_A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire or without a valid preexisting patient-practitioner relationship._

Prescriptions based solely on an internet-based questionnaire or that are issued without a valid preexisting patient-practitioner relationship are not valid in Missouri and cannot be filled, regardless of the location of the prescriber.

**E.13 PRESCRIPTION TRANSFERS (ORIGINALS & REFILLS)**

Upon request, a prescription must be transferred if: (1) the prescription is still valid and (2) the number of lawfully allowed refills has not been reached [**20 CSR 2220-2.120**]. Transfer may be requested by the patient or by another pharmacy at the patient’s request. Transfer is mandatory and must be completed within one (1) business day of the patient’s request [**20 CSR 2220-2.120(3)**].

Prescriptions may only be transferred to or from a pharmacy licensed in a U.S. state/territory [**20 CSR 2220-2.120(1)**]. Prescriptions may not be transferred to an unlicensed entity or a pharmacy not located in a U.S. state/territory.

The transferring and receiving pharmacy must record:

<table>
<thead>
<tr>
<th>TRANSFERRING PHARMACY</th>
<th>RECEIVING PHARMACY</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ The name of the pharmacy receiving the transfer;</td>
<td>✓ All information required for an original prescription;</td>
</tr>
</tbody>
</table>
Electronic transfers of non-controlled prescriptions are allowed if the pharmacies are under the same ownership and share the same database. The prescription may be transferred by generating a computer-based report at the transferring pharmacy of the prescription(s) transferred out [20 CSR 2220-2.120(2)(B)8]. The transfer record must be readily retrievable and must include all information required by 20 CSR 2220-2.120.

If a prescription is transferred, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the pharmacy, the prescription must be treated as a new record, showing the original date written and original expiration date [20 CSR 2220-2.080(9)].

The Board is aware of pharmacies improperly denying transfers due to pharmacy disputes, unpaid patient accounts/bills or early refills. Legally valid transfer requests are mandatory. If the refill is too soon, the transferring pharmacy may call attention to the early refill but cannot refuse to transfer. The receiving pharmacy is responsible for reviewing the prescription before dispensing to prevent unauthorized refills.

Under 20 CSR 2220-2.140(5)(D), refills associated with a nursing home order are not valid for transfer or use outside of the facility.

Controlled Substances: The following general requirements apply to controlled substance refill transfers:

- Schedule II controlled substances may not be transferred. [20 CSR 2220-2.120(1)(B)].
- Schedule III-V controlled substances may be transferred, however, transfer information may only be communicated between licensed pharmacists. [20 CSR 2220-2.120(1)(D)]. Pharmacy technicians or intern pharmacists may not provide or receive controlled substance transfers.
- Schedule III – V controlled substance prescriptions may only be transferred one time. [20 CSR 2220-2.120(1)(E)]. However, additional transfers are allowed if the pharmacies electronically share a real-time, online database. [20 CSR 2220-2.120(1)(E)].

Pharmacies electronically transferring controlled substance refills need to be aware that 20 CSR 2220-2.120 and DEA regulation 21 CFR 1306.25 require that all information for controlled substance refills must be transferred directly between two pharmacists. The transfer of controlled substance refills without the direct involvement of two pharmacists is prohibited— even if the pharmacies share a common database or have a Class J Shared Services arrangement.

The DEA reiterated their position in the March 31, 2010 Federal Register, page 16268, where the DEA commented: "DEA has never permitted the transfer of controlled substance prescriptions without the
involvement of two licensed pharmacists, regardless of whether the two pharmacies share a common database.” Licensees should review their transfer procedures to ensure compliance with controlled substance laws.

E.14 PRESCRIPTION NUMBERING

Prescriptions must be consecutively numbered or assigned a unique, readily retrievable identifier. [20 CSR 2220-2.010(2); 20 CSR 2220-2.017]. The Board anticipates further defining a “unique identifier” by rule. In the interim, prescriptions should be uniquely labeled in a manner that allows individual retrieval.
F.1 GENERAL REQUIREMENTS

Licensees may lawfully dispense medication pursuant to a valid patient-specific prescription or a prescription drug order from an authorized prescriber. Class-B pharmacies may also dispense based on a medication order. Intern pharmacists and pharmacy technicians may assist with dispensing, however, all activities must be supervised by a pharmacist. [20 CSR 2220-2.010(1)(B)]. A Missouri-licensed pharmacist must inspect and verify the prescription’s accuracy prior to dispensing, including the contents and the affixed label. [20 CSR 2220-2.010(1)(B)]. See E.16 for automated filling systems.

Licensees should take proactive steps to prevent and detect errors. The Board encourages licensees to report dispensing errors to the USP-ISMP Medication Errors Reporting Program. This confidential program gathers and analyzes data to help prevent future errors. Reports may be submitted online at www.ismp.org.

The Board has been asked about shipping prescriptions to patients located in a foreign country or outside of the United States. The Board’s rules would not prohibit dispensing to patients outside of the United States, however, licensees should consult with the FDA and the applicable country/territory to ensure compliance with federal and international laws. Licensees should also consult with BNDD and the DEA if controlled substances are involved.

F.2 AUTHORIZED MEDICATION SOURCES

Licensees may only dispense medication that is received from: (1) a Missouri-licensed drug distributor, (2) a Missouri licensed pharmacy or (3) a pharmacy licensed in another U.S. state or territory. If medication is received from a non-resident pharmacy that is not licensed in Missouri, the total amount of medication distributed/received cannot exceed five-percent (5%) of the pharmacy’s total annual prescription drug sales. [§ 338.315.2] The receiving Missouri pharmacy must maintain proof the non-resident pharmacy has a current pharmacy license in the state/territory where the drug is shipped/distributed from.

Medication receipts/transfers must be documented by invoice (non-controlled and schedule III-V drugs) or via a DEA 222 form or CSOS (schedule II drugs). For medication received from a non-resident pharmacy that is not licensed in Missouri, an invoice record must also be maintained which documents the name and address of the non-resident pharmacy, the purchase/transfer date and the name, strength, and quantity of the drug received. See rule 20 CSR 2220-5.020(1) for additional drug distribution exemptions.

F.3 DRUG SAMPLES

Unless otherwise allowed by federal law, drug samples may not be dispensed by, or maintained in, the pharmacy. [20 CSR 2220-2.010(8)].

F.4 LABELING

A written label must be affixed to each prescription container dispensed to a consumer indicating:

1) The date the prescription was filled;
2) A prescription number or other unique identifier;
3) The patient's name;
4) The prescriber's directions for usage;
5) The prescriber's name (see below for APRNs, Assistant Physicians & Physician Assistants);
6) The pharmacy’s name and address (For Class-J pharmacies, either the name and address of the pharmacy responsible for offering patient counseling may be listed on the label or the...
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Pharmacy responsible for dispensing to the patient may be listed on the label as designated by the pharmacies by contract;

7) The exact name and dosage of the drug dispensed, and;
8) If a generic substitution is made, the manufacturer must be identified on the label or in the pharmacy’s records by name or abbreviation. [§ 338.059].

For controlled substance prescriptions issued by APRNs, or physician assistants, the label must include both the names of the prescribing mid-level practitioner and their supervising or collaborating physician. [§ 195.100, RSMo]. Note: This pertains to “prescriptions” and not to internal drug “orders” for in-patients of a licensed hospital.

Missouri law does not prohibit the addition of other label information. However, prescription labels should be clear and easily readable.

F.5 PATIENT COUNSELING

Patients must be offered the opportunity to consult with a Missouri-licensed pharmacist each time a prescription is dispensed (new or refill). [20 CSR 2220-2.190]. If the medication is delivered or mailed to the patient, a written offer to counsel must be provided with the patient’s medication along with a toll-free telephone number for the dispensing pharmacy. [20 CSR 2220-2.190(1)].

The offer to counsel may be extended by pharmacy staff. However, counseling may only be provided by a Missouri-licensed pharmacist or a Missouri-licensed intern pharmacist acting under the pharmacist’s immediate supervision. [20 CSR 2220-2.190].

Counseling should focus on enhancing or optimizing drug therapy and promoting safe/appropriate medication use. [20 CSR 2220-2.190]. At a minimum, pharmacists must provide any counseling required by state/federal law.

To facilitate counseling, licensees are required to collect and maintain appropriate patient information. Appropriate information may include, but is not limited to, the patient’s name, address, telephone number, age, gender, clinical information, disease states, allergies and a list of other drugs prescribed. [20 CSR 2220-2.190(2)].

The Board is aware of instances where delivery drivers are delivering medication to the patient and verbally offering patient counseling that is subsequently provided by a pharmacist electronically or on the phone. A toll-free number and written offer to counsel is not required in these instances if a verbal offer is given to the medication recipient and the patient is able to consult with a pharmacist at the time the prescription is delivered either electronically or verbally.

Patient counseling is not required if:

- The patient is an inpatient of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications, or;
- The patient or caregiver refuses consultation. [20 CSR 2220-2.190(4), (5)].

F.6 GENERIC SUBSTITUTION [§ 338.056]

Unless otherwise requested by the patient, a pharmacist may substitute a generic equivalent if:
• The drug substituted is not listed as therapeutically inequivalent to the product prescribed in the FDA’s Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book);
• The generic substitution costs less than the prescribed product; and
• The prescriber authorized substitution. Authorization may be provided orally, electronically or by signing the “Substitution Permitted” line on the prescription. [§ 338.056]. For non-Missouri prescribers, substitution would be governed by the prescriber’s licensing state/territory.

If a generic product is substituted, the manufacturer’s name or abbreviation must be identified on the prescription label or in the pharmacy’s records.

![Printing only a brand name on a dispensing label when a generic product is dispensed is misleading to the public and considered misbranding. Some licensees list the generic product on the label and then use the statement “substituted for” with the brand name of the product that is being substituted. This is acceptable if the label is not misleading. However, there is no law requiring that a brand name be on a label when a substitution is made.]

F.7 INTERCHANGEABLE BIOLOGICAL PRODUCTS [§ 338.055, § 338.056]

Pharmacists may substitute an interchangeable biological product for a prescribed biological product if substitution has been authorized by the prescriber. [See § 338.056, § 338.085]. An “interchangeable biological product” is defined as a biological product that the Food and Drug Administration:

a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. Section 262(k)(4); or
b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). [ § 338.085.1]

The FDA’s list of interchangeable biologicals may be found at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm (Purple Book).

Pharmacists must inform the patient that an interchangeable biological product has been substituted either verbally or in writing. [§ 338.085.2]. Additionally, pharmacists must notify the prescriber of the product name and manufacturer within five (5) days of dispensing either electronically, verbally or in writing. Prescriber notification is not required if there is no FDA approved interchangeable biological product for the product prescribed or the prescription is a refill and no changes have been made from the prior filling. [§ 338.085.3]

Substitution of interchangeable biological products must comply with all other Board rules applicable to generic substitutions, including, all labeling and recordkeeping requirements.

F.8 CONSOLIDATION OF REFILLS [§ 338.202]

Section 338.202, RSMo, allows a pharmacist to consolidate refills of non-controlled maintenance medication in a single filling. “Maintenance medication” is defined as a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis. To consolidate, the maintenance medication must have been previously prescribed to the patient for at least a three-month period.

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Pharmacists may dispense up to the total number of authorized dosage units, however, no more than a 90-day supply may be dispensed at one time.

Consolidation is not allowed if the prescriber indicates on the prescription that dispensing the initial amount followed by periodic refills is medically necessary. Additionally, controlled substances cannot be consolidated.

The Board has been asked if the required 3-month patient use period has to be consecutive or if prior fills/refills must have been dispensed by the same pharmacy. Missouri law is silent on both of these questions. Absent further statutory clarification, it appears licensees may consolidate refills for patients prescribed a maintenance medication for any 3-month period even if prior fills/refills were dispensed by another pharmacy.

Pharmacists should exercise their professional judgment when consolidating refills as consolidation may not be appropriate for all patients. The Board suggests advising patients of any additional costs/insurance requirements prior to dispensing.

**F.9 OFFICE STOCK DISPENSING**

To be valid for dispensing, a prescription must be written by an authorized prescriber for a specific patient. [§ 338.095]. Pharmacies/pharmacists are NOT allowed to dispense drug products for office stock by prescription.

Pharmacies may, however, transfer medication by invoice (non-controlled and schedule III-V drugs) or via a DEA 222 form or CSOS (Schedule II drugs). [See E.14 for additional information on drug transfers]. A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy’s total gross sales. Total gross sales are calculated based on the pharmacy’s total annual prescription drug sales, or if prescriptions are not sold, 5% of the pharmacy’s total drug purchases. [§ 338.330(2); 20 CSR 2220-5.020(1)(B)]. See C.18 for Class B pharmacy exemptions.

Pharmacies may need to be registered with the FDA as a repackager if the pharmacy repackages drugs for distribution to other pharmacies or practitioners. Additionally, a pharmacy may be required to register with the DEA as a controlled substances distributor under federal law if the total dosage units of controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed during the previous calendar year.

The federal Drug Quality and Security Act (DQSA) requires entities distributing non-patient specific compounded preparations to register with the FDA as a drug manufacturer or a section 503(b) outsourcer. Licensees should consult legal counsel to ensure compliance. Failure to comply with state/federal law constitutes ground for legal/disciplinary action by the Board.

**F.10 PRESCRIPTION DELIVERY SITES**

Pursuant to 20 CSR 2220-2.013, prescriptions filled by a Missouri pharmacy “may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy.” However, filled prescriptions may be delivered to the following locations at the request of the patient or the patient’s authorized designee:
• The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;
• A long-term care facility as defined by 20 CSR 2220-2.140 where the patient resides;
• A hospital, office, clinic or other medical institution that provides health care services;
• A residence designated by the patient or the patient’s authorized designee, or;
• The patient’s office or place of employment.

Prescriptions may be delivered to other non-pharmacy locations not specified in the rule only if the prescription is delivered directly to the patient or the patient’s authorized designee.

Patient/designee authorization may be received verbally, electronically or in writing. The Board recommends documenting patient authorization and the requested location in the pharmacy’s prescription records. Except as otherwise authorized for long-term care facilities, prescriptions left at a non-pharmacy location cannot be returned to stock if not picked up by the patient. Rule 20 CSR 2220-2.013 applies to all Missouri licensed pharmacies delivering filled prescriptions regardless of delivery method (e.g., mail order, employee delivery or common carrier).

Pharmacies delivering medication as allowed by the rule must develop written policies and procedures “to ensure the safe and appropriate delivery of prescription drugs within the temperature ranges recommended by the manufacturer” or USP. The Board understands licensees cannot control or predict the activities of third party carriers. The Board also recognizes extenuating circumstances may occur that are beyond a licensee’s controls. Licensees should establish policies and procedures to ensure delivery within appropriate temperature requirements given normal and customary delivery times. The Board also recommends establishing a mechanism for patients to contact the pharmacy with delivery concerns.

Policies and procedures should be maintained at the pharmacy or accessible for review on request or during an inspection. A prescription delivery policy/procedure is not required if the pharmacy does not deliver filled prescriptions.

Controlled Substances: Licensees must comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security requirements. Please contact the DEA or BNDD for additional questions.

Prescriptions for Veterinary Use: At the request of a customer, legally filled prescriptions for veterinary use may be delivered to a residence, business, or clinic designated by the customer.

✓ Can pharmacies deliver to drop sites? No. Prescriptions may only be delivered to a site not specified in the rule if the prescription is delivered directly to the patient or the patient’s authorized designee.
✓ Prescriptions may be delivered to another pharmacy for dispensing/patient pickup if both pharmacies are in compliance with 20 CSR 2220-2.650 and Class J: Shared Services standards.

F.11 MISBRANDING/ADULTERATION

State and federal law prohibits dispensing any misbranded or adulterated substance. The Board defines “misbranded” and “adulteration” consistent with state and federal law, including, but not limited to, Sections 501 and 502 of the Food, Drug and Cosmetic Act [21 USC § 351, § 352], § 196.095 and § 196.100, RSMo.
Outdated, distressed, misbranded or adulterated drugs must be physically separated from the active inventory and maintained in a separate area. [20 CSR 2220-2.090(2)(V)]. Segregated areas must be adequately marked or identified to ensure outdated, misbranded or adulterated drugs do not re-enter the pharmacy’s active inventory.

✓ **Reheating/Resealing:** The Board has received questions regarding sealing/resealing drugs more than once in the type of packaging where intense heat is utilized to seal the packaging (e.g., blister cards). USP discourages the practice because the effect of reheating on the medication is unknown. As noted by USP, several manufacturers also recommend against heat sealing drugs more than once. In accordance with USP, the Board discourages the practice.

**F.12 EARLY FILLS/REFILLS**

Board inspectors have observed medications being dispensed too soon to the same patient. In some instances, “early fills/refills” may result from processing prescriptions from different prescribers or refilling a prescription on a cycle that does not correlate with previously dispensed amounts. Under state and federal law, pharmacists have a professional obligation to ensure drugs are dispensed for bona fide purposes and are not being abused or diverted due to excessive purchases. Licensees should review patient records to ensure compliance with prescribed directions and to prevent excessive dispensing.

**F.13 CHILD RESISTANT CONTAINERS**

The Board has signed an agreement with the Consumer Product Safety Commission (“CPSC”) to assist in enforcing child resistant container laws. All dispensed prescriptions must be packaged in a child resistant container. A non-child resistant container may be issued if:

- The physician specifically requests that a non-child resistant container be dispensed. Pharmacists cannot honor blanket requests from a prescriber to never use safety caps for the prescriber’s patients, or;
- The patient specifically requests a non-child resistant container. Patients may issue a blanket request for all prescriptions. However, a request on a single prescription cannot be used as a blanket waiver for subsequent prescriptions. The Board recommends documenting patient requests in writing.

The Board is required to report significant violations of the child resistant container laws to the CPSC. Under federal law, violations may result in criminal or civil liability. The pharmacy related provisions of the Poison Prevention Packaging Act can be found at 16 CFR 1700.14.

**F.14 TABLET SPLITTING**

A number of insurance plans and their agents require tablet splitting. Generally, pharmacists have been asked to:

- Dispense double the strength of a prescribed drug and then split the tablets in half for the delivery of the original intended dose. After splitting the tablets, the pharmacist makes changes to the directions to coincide with the change in tablet strength, or;
- Supply a drug in whole form and change the label directions to indicate that half of a tablet is to be administered for each dose. Some insurance plans are requiring that tablets with coatings or non-scored tablets be dispensed with the expectation that they be split.

The Board is concerned that these practices may not be in the patient’s best interest. As licensed professionals, pharmacists must provide medications in their proper form. Only drug products that are...
scored should be used in tablet splitting. This includes splitting tablets into half or quarter tablets. Drugs that are not scored will likely not split in a manner that will provide a uniform dose. Coated tablets may also present problems because once the drug is split, any effect the coating provides may be compromised.

Before tablet splitting, pharmacists should verify that:

1) The literature, or other recognized compendia for the drug, recognizes or indicates that splitting of the specific brand of tablet can be accomplished safely and effectively;
2) The prescriber has approved any change in the prescription if a strength higher than that originally prescribed is used. The prescriber must authorize dispensing a higher strength, and;
3) The patient has received detailed patient counseling to ensure the patient understands the changes made. If the patient is responsible for splitting the tablet, counseling should be provided on splitting techniques and the use of any related items (e.g., tablet splitters).

F.15 PREPACKAGING [20 CSR 2220-2.130]

To assist in dispensing, medication may be removed from the original manufacturer’s container and placed in a dispensing container/system where the medication will be stored until dispensed to a patient (e.g., an automatic dispensing system). Only products that will be directly provided to the patient may be prepackaged.

Proper sanitation procedures must be utilized when prepackaging drugs. Drugs should not be handled with bare hands. Additionally, containers and equipment must be properly cleaned and maintained to prevent contamination. Reusable containers should be kept clean of tablet dust and other contaminants.

At a minimum, containers used for prepackaging must meet USP Class B container standards. Light sensitive containers must be used, if applicable. A label must be affixed to the prepacked drug container indicating the drug’s name and strength, the manufacturer/distributor, lot number, and the required expiration date. The maximum allowed expiration date is twelve (12) months or the manufacturer’s expiration date, whichever is less. In lieu of the required label, licensees that store drugs in an automated counting device may record the required lot number/expiration date in the pharmacy’s records, provided the information must be fully traceable and readily retrievable during an inspection.

F.16 PATIENT MED PAKS [20 CSR 2220-2.145]

In lieu of dispensing multiple containers, licensees may dispense multiple medications in a single customized patient medication package (“patient med pak”). Patient med paks must comply with rule 20 CSR 2220-2.145. An authorized “patient med pak” is defined as a package prepared for a specific patient that consists of one or more containers which contain two (2) or more prescribed drugs. Patient med paks may only be used for solid oral dosage forms (e.g., tablets). Med paks may not contain controlled substances.

Prior to dispensing a med pak, pharmacists must consider:

- Any applicable compendia requirements or guidelines;
- The physical and chemical compatibility of the dosage forms placed in each container; and
- Any therapeutic incompatibilities if the medications are administered simultaneously. The Board encourages licensees to report any observed or reported incompatibilities to USP.

**Containers:** Med Pak containers must be non-reclosable or designed to show if the container has been opened. Containers must comply with the moisture permeation requirements for a Class B single-unit or
unit-dose container, unless more stringent requirements exist for a drug contained in the med pak. USP has warned about potential physical and/or chemical incompatibilities when certain drugs are packaged together. Pharmacists must ensure that no interactions will occur when preparing multi-med packages.

**Labeling:** Med paks must be designed or each container labeled to indicate the day and time or period of time that the contents in each container should be taken. Med paks must also bear a label indicating:

1. The patient’s name;
2. A serial number for the patient med pak and a separate serial number for each prescription order for each drug contained in the med pak;
3. The name, strength, physical description or identification and total quantity of each drug product;
4. Directions for use and any cautionary statements contained in the prescription order for each drug;
5. Any storage instructions or cautionary statements required by the official compendia;
6. The name of the prescriber for each drug product;
7. The preparation date and beyond-use date assigned. The beyond-use date may be no later than sixty (60) days from the date of preparation;
8. The name, address, and telephone number of the dispenser; and
9. Any other information, statements, or warnings required for any drug included.

If intact containers can be removed or separated from the patient med pak, each individual container must contain a label that identifies all medication in the container.

**Package Inserts:** Package inserts/medication guides must be provided if required for any drug in the med pak. In lieu of an individual insert, required information may be incorporated into a single, overall insert for the entire med pak.

**Records:** In addition to the prescription, records must be maintained for each med pak dispensed. Records must include:

1. The patient’s name and address;
2. The prescription serial number for each drug contained in the med pak;
3. The name of the manufacturer/labeler and lot number for each drug;
4. The preparation date and the assigned beyond-use date;
5. Any special labeling instructions;
6. The name or initials of the preparing pharmacist; and
7. Information identifying or describing the design, characteristics, or specifications of the med pak. The med pak must be described in a manner that would allow an identical med pak to be made.

**Returns:** Generally, med paks that have been delivered to an institution or to a patient cannot be returned to the pharmacy. However, 20 CSR 2220-2.145 provides a pharmacist may modify/repackage a med pak that has been delivered to an institution or patient if:

1. The med pak is returned to the pharmacy that originally dispensed the med pak;
2. The med pak is modified/repackaged per prescription order for the same patient to whom it was originally dispensed;
3. The med pak is labeled in compliance with 20 CSR 2220-2.145. The med pak must retain the original beyond use date assigned to the med pak before modification/ repackaging;
4. The med pak is assigned a new serial number, and;
5) The medications removed from the med pak are destroyed in compliance with state and federal law. Removed meds CANNOT be returned to stock or redispensed to either the same or a different patient.

Pharmacists modifying/repackaging medication pursuant to 20 CSR 2220-2.145 must comply with all applicable record keeping requirements.

Except as otherwise allowed by 20 CSR 2220-2.145 for modification/repackaging purposes, medication that has been commingled with other drugs in a med pak may not be returned to stock, dispensed, or distributed except for destruction.

**Compliance with 20 CSR 2220-2.145 is required even if the container is supplied by the patient.**

**F.17 RETURN, REUSE & DISPOSAL**

*Return To Stock [20 CSR 2220-3.040]:* A prescription may be returned to stock if:

1) The patient did not receive the prescription; and
2) The prescription was maintained in the pharmacy’s possession in accordance with the manufacturer’s labeled storage requirements at all times.

The prescription must be maintained in the original patient container with the name of the drug, dispensing date and the prescription number visible on the container. Notations may be made on the label to distinguish it from active prescriptions being processed.

If returned to stock, the drug’s expiration date must become the lesser of one (1) year from the dispensing date on the label or the manufacturer’s original expiration date, if known. The pharmacy must delete the dispensing in the pharmacy’s records and reverse/credit any third party payor claims (e.g., insurance).

**Drugs returned to stock may not be poured back into the original stock container because the drug has undergone manipulation outside of its original container. The mixing of lot numbers is also prohibited. Drugs returned to a stock container will be deemed misbranded and/or adulterated in violation of state and federal law.**

*Errors/Recalls:* As authorized by federal law, the Board has allowed returns to the pharmacy if the wrong medication was dispensed to the patient or in instances of a drug recall. In no instance may returned medication be reused or returned to stock. [20 CSR 2220-3.040(3)].

*Long-Term Care/Hospice Facilities and Hospitals:* See M-5 for authorized returns from a long-term care facility or from a hospital or a hospice facility regulated by the Missouri Department of Health and Senior Services.

*Returns for Disposal:* In 2017, the Board promulgated 20 CSR 2220-2.095 which authorizes pharmacists to collect medication for destruction. The following is a basic summary of the rule:

- Pharmacies may provide a collection receptacle or establish an authorized mail-back program to accept medication from the public. Board notification or registration is not required. However, participating pharmacies must establish and follow policies and procedures for collecting/destroying medication. Participation is voluntary; pharmacies are not required to establish a drug collection program.
• Collected medication must be destroyed and cannot be resold or reused under any circumstances.
• Medication may be accepted from any member of the public (see below for controlled substances). However, collection receptacles or mail-back programs cannot be used to dispose of unused/unwanted medication in the pharmacy’s inventory (e.g., expired medication, medical waste).
• Collection receptacles must be securely placed and maintained inside the pharmacy’s physical building in a manner that prevents theft, diversion or unauthorized removal. Receptacles must be securely locked, substantially constructed containers that are equipped with inner liners for storing medication. Receptacles must be visible to pharmacy staff at all times and may not be located in or near exit doors.
• For mail-back programs, the public must be provided pre-addressed, postage-paid mail-back packages for returning medication. Mail-back packages must be nondescript and cannot include any markings or other information that might indicate the packages contain medication. Each package must include a unique identification number or other unique identifier to enable tracking.
• Mail-back packages cannot be returned to the pharmacy. Instead, packages must be directly mailed to a collector that is authorized by the DEA or other federal law to destroy medication (e.g., a reverse distributor). Consumers cannot be required to provide personally identifiable information when mailing back medication.
• Collection receptacles may be placed at a long-term care facility for use by the public or facility residents. The new rule does not apply to medication collected for return and reuse as authorized by the Board’s return and reuse rule (20 CSR 2220-3.040).
• Collected medication must be rendered non-retrievable and destroyed in compliance with all applicable federal and state laws. Destruction may occur at the pharmacy or destroyed offsite by an entity authorized to destroy medication under state and federal law.
• Destruction records and inventories of inner-liners must be maintained for two (2) years and available on inspection/request (see rule for specific recordkeeping requirements).
• The rule does not apply to or restrict licensees/permit holders from participating in medication collection programs operated by law enforcement agencies (e.g., DEA or police/sheriff “take back” days), provided: (1) law enforcement personnel are present whenever drugs are collected or on-site, (2) collected medication is placed into a collection container that is supervised by law enforcement at all times and, (3) collected medication remains under the control of, and is removed by, law enforcement.

This list is not exhaustive; additional requirements exist that are not listed above. Licensees should review 20 CSR 2220-2.095 in its entirety to ensure compliance

**Controlled Substances:**

BNDD is in the process of revising its statutes/rules to align with DEA standards for collecting controlled substances for destruction. Additionally, § 195.070.4, RSMo, provides a pharmacy “shall not accept any portion of a controlled substance unused by a patient, for any reason, if such practitioner did not originally dispense the drug.” Pending final rulemaking/legislative changes, BNDD recommends that
licensees consult with legal counsel to ensure compliance with state and federal law, including, the DEA’s Disposal of Controlled Substances rule.

F.18 DISTRIBUTING vs. DISPENSING [§ 338.333, § 338.330]

Pharmacies may transfer legend drugs or drug-related devices to another pharmacy or an authorized prescriber by invoice (schedule III-V drugs/non- controlleds) or via a paper/electronic DEA 222 form or CSOS (schedule II drugs). Prescriptions cannot be used to transfer drugs to a pharmacy or prescriber. A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy’s total gross sales. Total gross sales are calculated based on the pharmacy’s total annual prescription drug sales, or if prescriptions are not sold, 5% of the pharmacy’s total purchases. [§ 338.330(2); 20 CSR 2220-5.020(1)(B)]. See C.18 for Class-B exemptions.

If medication is transferred by invoice, the pharmacy’s invoice record must include:

- Date of distribution;
- Product name/strength;
- Quantity;
- The names/address of the parties; and
- If a controlled substance, DEA numbers for both the transferring pharmacy and the recipient.

Invoices must be maintained in the pharmacy’s records separately from prescription records.

Controlled substance transfers must comply with federal/state controlled substance laws. Pharmacies may not repackage drugs for distribution to other pharmacies or practitioners without being registered with the FDA as a repackager.

Pharmacies that “borrow” or “loan” medication amongst themselves must maintain records of the transactions (invoice/DEA-222). In a borrowing and payback scenario, the pharmacy must have two transaction records: one record documenting receipt of the products and one record documenting the return of the product. The same documentation must be maintained by the pharmacy loaning the product. Intra-store transfers must also be recorded/documented.

F.19 VACUUM TUBE DELIVERY SYSTEMS [20 CSR 2220-2.800]

Vacuum tube systems may be used to deliver medication to a patient if the system is designed and engineered to ensure drug security and to ensure that drugs are correctly and efficiently delivered. The system must be dedicated solely to delivering drugs from within a licensed pharmacy and cannot be used for other departments or combined/ attached to any other system (e.g., grocery delivery). The system must be turned off and medication may not be delivered if the pharmacy is closed or when there is no pharmacist on duty.

Vacuum tube systems must allow pharmacy personnel and the consumer to communicate effectively both orally and in writing. A direct and identifiable line of sight must be maintained with the consumer. Alternatively, a video camera and audio system may be used to identify consumers. The video monitor/audio system must be in good working order or use must be discontinued until corrections/repairs are made. At a minimum, video monitors must be at least twelve inches (12”) wide. Backlighting or other factors that may inhibit video/audio performance must be considered.

The patient’s identification must be verified before drugs are delivered. To prevent confusion, the Board recommends using multiple identifiers (e.g., birth date, address). [See 20 CSR 2220-2.800(2) for vacuum systems installed before September 1, 1988].
F.20  AUTOMATED FILLING SYSTEMS [20 CSR 2220-2.950]

Rule 20 CSR 2220-2.950 establishes requirements for pharmacists using an automated filling system (AFS) to dispense prescriptions. An AFS is defined as “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 AFS does not include: (1) automated devices used solely to count medication (counting devices), (2) vacuum tube drug delivery systems governed by 20 CSR 2220-2.800 or (3) automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to a patient.

A pharmacist must inspect and verify the contents and label of every prescription filled by an AFS unless:

- A pharmacist verifies the accuracy of the prescription data used by or entered into the AFS for the specific patient prior to filling. The identity of the verifying pharmacist must be documented in the pharmacy’s records and maintained for five years [20 CSR 2220-2.950(4)(C)]; and
- A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was loaded in the AFS before initiating the fill process. [20 CSR 2220-2.950(4)(D)]. An electronic verification system may be used to verify manufacturer unit of use packages or repacked medication previously verified by a pharmacist.*  Repacked containers must comply with 20 CSR 2220-2.130; and
- The filling process is fully automated from the time the process is initiated until a completed prescription is produced that is ready for dispensing to the patient. [20 CSR 2220-2.950(4)(B)]. In other words, AFS must fill, label, and seal the prescription in the container or the prescription must be dispensed by the AFS in a manufacturer’s unit of use package or a repacked pharmacy container. [20 CSR 2220-2.950(4)(E)]. No manual intervention with the medication or prescription may occur after the medication is loaded into the AFS. Pharmacy staff may prepare or package the final labeled product container for mailing, storage or delivery. However, no other manual intervention is allowed; and
- 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 [20 CSR 2220-2.950(4)(F)]; and;*
- Daily random quality testing is conducted by a pharmacist on at least two percent (2%) of the prescriptions filled by the AFS on the date tested or filled by the AFS on the last day of system operation. The pharmacist-in-charge must determine how the sample is selected. Proof of compliance, random quality testing date(s) and testing results must be documented and maintained in the pharmacy’s records and available for inspection. [20 CSR 2220-2.950(4)(G)]

* Electronic verification systems must comply with 20 CSR 2220-2.950(1)(B). Video/camera verification systems alone do not qualify as electronic verification systems.

Significantly, pharmacies using an AFS in lieu of physical pharmacist verification must test the system before initial use, when restarting the system or after any modification to the AFS or electronic verification system has been made that may change or alter the filling/electronic verification process.

Pharmacies using an AFS in lieu of physical product inspection/verification by a pharmacist must maintain written policies and procedures to monitor and ensure the AFS is functioning properly and safely. 20 CSR 2220-2.950(5) contains a detailed listing of minimum policy/procedure requirements. Policies/procedures must address:

- System maintenance
- Accurate loading
SECTION E: MEDICATION DISPENSING

- Sanitation, cross-contamination
- Expired/recall drugs
- Errors and malfunctions
- Testing
- Training
- System Access
- Tracking responsible persons
- Quality Assurance

AFS policies and procedures must be reviewed annually and maintained in the pharmacy’s records for at least two (2) years.

The required AFS policies and procedures and mandatory testing only apply if a pharmacist is not physically inspecting and verifying the final product. Pharmacies physically verifying the final contents and label of medication filled or packaged by an AFS are not subject to the additional requirements of 20 CSR 2220-2.950(4) – (6).

F.21 EMERGENCY PHARMACIST DISPENSING [§ 338.200]

Section § 338.200, RSMo, authorizes a Missouri pharmacist to dispense an emergency supply of medication if the pharmacist is unable to obtain refill authorization from the prescriber. Pharmacists may dispense an emergency supply if:

- In the pharmacist’s professional judgment, interruption of therapy might reasonably produce undesirable consequences;
- The pharmacy previously dispensed or refilled a prescription from the prescriber for the same patient and medication;
- The pharmacist informs the patient or the patient’s agent at the time of dispensing that prescriber authorization is required for future refills. Notification can be made verbally, electronically or in writing, and;
- The emergency dispensing is documented in the patient’s prescription record.
- The drug is not a controlled substance.

The emergency supply must be limited to the amount needed for the emergency period as determined by the pharmacist within his or her professional judgment. However, the total amount dispensed cannot exceed a seven-day supply. If the prescriber is deceased, incapacitated or unable to provide medical services, up to a thirty-day supply may be dispensed.

Notification must be promptly provided to the prescriber or the prescriber’s authorized agent after an emergency dispensing. An emergency supply may not be dispensed if the pharmacist has knowledge that the prescriber has prohibited or restricted emergency dispensing to the patient.

The Board recognizes some medications are dispensed in manufacturer packaging that exceeds a seven day supply. However, § 338.200.2 provides the amount dispensed shall “not exceed a seven day supply” if the prescriber is not deceased or otherwise incapacitated. The Board recommends that pharmacists consult with legal counsel and use their professional judgment as needed for the emergency period in such circumstances.

F.22 NALOXONE DISPENSING

Effective August 28, 2017, Missouri pharmacists may dispense an “opioid antagonist” without a prescription:

- Under protocol with a Missouri licensed physician, or
- Pursuant to a statewide standing order issued/approved by the Missouri Department of Health and Senior Services (“DHSS”). [§ 195.206.3]
An “opioid antagonist” is defined as:

*An opioid antagonist is defined as:*

*Naloxone hydrochloride that blocks the effects of an opioid overdose that is administered in a manner approved by the United States Food and Drug Administration or any accepted medical practice method of administering.* [§ 195.206, RSMo]

The allowance applies to all currently licensed Missouri pharmacists; No additional Board or DHSS licensure, certification or training is required. However, pharmacists should educate themselves on proper naloxone use and administration before dispensing.

A variety of naloxone educational materials are available on the Board’s website, including:

- The [Opioid Overdose Prevention Toolkit](http://www.sahmsa.gov) published by the United States Substance Abuse and Mental Health Services Administration (SAHMSA), and
- [An Opioid Safety and Naloxone Brochure](http://www.sahmsa.gov) for Missouri patients and caregivers.

(Complimentary copies can be requested by e-mailing MissouriBOP@pr.mo.gov or by contacting the Board office. Quantities may be limited).

### Dispensing by Protocol

Pharmacists dispensing naloxone by protocol must have a protocol with a licensed physician that authorizes the pharmacist to dispense without a prescription. The Board anticipates reviewing applicable protocol standards in the future. In the interim, the Board suggests that naloxone protocols include provisions/requirements for:

- Pharmacist education and training
- Emergency notification and documentation
- Patient education and counseling, and
- Protocol review, signatures and timeframe.

A [sample protocol template](http://www.sahmsa.gov) is available on the Board’s website. Licensees should maintain proof of the authorizing physician’s licensure in the pharmacy’s records.

Section 195.206, allows any individual or entity to purchase naloxone and does not include dispensing limits or quantity restrictions. However, the pharmacist’s protocol may include additional restrictions. If naloxone is sold as a distribution, the Board recommends that pharmacies document the lot number, expiration date and the patient’s name. However, the patient’s name is not required to distribute naloxone if the patient refuses to provide one.

If dispensed by protocol as a prescription, a prescription label that complies with § 338.059, RSMo, must be attached. If sold as a distribution, the Board recommends that pharmacies document the lot number, expiration date and the patient’s name.

All naloxone sales/dispensing must be documented in the pharmacy’s records. If dispensing as a prescription, all prescription recordkeeping requirements apply and a § 338.059 compliant prescription label must be attached. If sold as a distribution, the pharmacy must have a record of the sale that should include:

- The transaction date
- Product name, strength and dosage form
- Quantity, and
- The names of the parties/entities, if known.
Sales/distribution records must be kept for two (2) years. Prescription records must be maintained for five (5) years.

**Dispensing by Standing Order**

The Missouri Department of Health and Senior Services issued a statewide naloxone order on August 28, 2017, that authorizes any Missouri licensed pharmacist to dispense naloxone without a prescription subject to the guidelines identified in the order. Unlike a protocol, pharmacists do not have to sign or negotiate a separate contract to participate in the standing order. A physician protocol is not required for pharmacists participating in the standing order. A copy of the standing order is available on the Naloxone Resources page on the Board’s website.

Under the standing order, naloxone can be dispensed to any “eligible candidate” which includes:

1. Individuals who voluntarily request naloxone and are at risk of experiencing an opiate-related overdose, including but not limited to:
   - Current illicit or non-medical opioid users or persons with a history of such use
   - Persons with a history of opioid intoxication or overdose and/or recipients of emergency medical care for acute opioid poisoning
   - Persons with a high dose opioid prescription (>50 morphine mg equivalents per day)
   - Persons with an opioid prescription and known or suspected concurrent alcohol use
   - Persons from opioid detoxification and mandatory abstinence programs
   - Persons entering methadone maintenance treatment programs (for addiction or pain)
   - Persons with opioid prescription and smoking/COPD or other respiratory illness or obstruction
   - Persons with an opioid prescription who also suffer from renal dysfunction, hepatic disease, cardiac disease, HIV/AIDS
   - Persons who may have difficulty accessing emergency medical services, or
   - Persons enrolled in prescription lock-in programs

2. Persons who voluntarily request naloxone and are the family member or friend of a person at risk of experiencing an opiate-related overdose, or

3. Persons who voluntarily request naloxone and are in the position to assist a person at risk of experiencing an opiate-related overdose.

Pharmacists should confirm patients are eligible candidates under the standing order prior to the sale/dispensing.

The Board has been asked if the patient’s name or address is required before dispensing. Patients are not required to give their name or address to purchase naloxone under the standing order. Additionally, DHSS and the Missouri Department of Mental Health have expressed concerns that patients may be discouraged from purchasing naloxone if they are asked for detailed personal data. Naloxone can save lives. Pharmacies are strongly encouraged to eliminate any unnecessary barriers or paperwork that might discourage citizens from seeking help.

This section references standing order requirements as of the date of this Practice Guide. The Naloxone standing order is subject to change as directed by the Missouri Department of Health and Senior Services. Licensees should review current requirements to ensure compliance with Missouri law.
**Section E: Medication Dispensing**

**Billing Insurance or Medicaid for Naloxone**

The Missouri Department of Insurance has advised that each insurance plan is different and may contain different billing requirements for Naloxone. Licensees should contact the patient’s insurance company for eligibility/payment questions, the Board cannot provide billing or insurance advice.

MO HealthNet has advised the Board that prescriptions for naloxone may be billed to MO HealthNet for eligible enrollees. Questions regarding MO HealthNet billing should be directed to MO HealthNet’s Pharmacy Help Desk at 800-392-8030.

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<table>
<thead>
<tr>
<th>Route(s) of Administration</th>
<th>Intranasal (IN) Preferred Method</th>
<th>Intramuscular (IM) Inject Into Shoulder or Thigh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication and Required Device for Administration</td>
<td>Naloxone HCl 1 mg/mL Inj. 2x2 mL as pre-filled Luer-Lock syringes  • Dispense two (2) doses Two (2) x Intranasal Mucosal Atomizing Devices (MAD 300)</td>
<td>Naloxone HCl 0.4 mg/mL Inj.  • 2 X 1mL single dose vials (SDV)  • 2 (two) 3 mL syringe  • 2 (two) 25 G, 1 inch needle</td>
</tr>
</tbody>
</table>

| Directions for Use | Call 911. Spray 1 mL in each nostril. Repeat every three minutes as needed if no or minimal response. | Call 911. Administer a single spray of NARCAN® in one nostril. Repeat every three minutes as needed if no or minimal response. | Call 911. Inject the entire solution of the vial or pre-filled syringe IM in shoulder or thigh. Repeat every three minutes as needed if no or minimal response. |

Refills may be dispensed as needed.

All naloxone sales/dispensing must be documented in the pharmacy’s records. If dispensing as a prescription, all prescription recordkeeping requirements apply and a § 338.059 compliant prescription label must be attached. If sold as a distribution, the pharmacy must have a record of the sale that should include:

- The transaction date
- Product name, strength and dosage form, and
- Quantity.

Every person sold/dispensed naloxone under the standing order must receive education regarding overdose risk factors, signs of an overdose, overdose response steps and naloxone use. Recommended educational materials are available at [http://mohopeproject.org/education](http://mohopeproject.org/education). A variety of resources and educational materials are also available online in the Board’s Naloxone Resource Center.

**Record Keeping:** Similar to dispensing by protocol, pharmacies must comply with all prescription recordkeeping requirements if naloxone is dispensed as a prescription. For other sales, the pharmacy must maintain a record of the sale that should include:
• The transaction date
• Product name, strength and dosage form, and
• Quantity.

Sales/distribution records must be kept for two (2) years. Prescription records must be maintained for five (5) years.

First Responder Agencies: Section 190.255 authorizes any licensed drug distributor or pharmacy to sell naloxone to a “qualified first responder agency” which is defined as “any state or local law enforcement agency, fire department or ambulance service that provides documented training to its staff related to the administration of naloxone in an apparent narcotic or opiate overdose situation.” A protocol is not required to provide naloxone to a qualifying first responder agency.

Naloxone sales to a qualified first responder agency should be documented by invoice. Prescriptions cannot be used to document the sale. Invoices should include:

a) The date of sale;
b) Product name;
c) Quantity Sold;
d) The identity of the qualified first responder agency; and
e) Names and address of both parties.

Invoices must be maintained in the pharmacy’s/distributor’s records and filed separately from prescription records.

The Board has been asked if a pharmacist needs to comply with 20 CSR 2220-6.040 to administer naloxone to a patient in an emergency overdose situation. Section 195.206 states:

6. Any person who administers an opioid antagonist to another person shall, immediately after administering the drug, contact emergency personnel. Any person who, acting in good faith and with reasonable care, administers an opioid antagonist to another person whom the person believes to be suffering an opioid-related overdose shall be immune from criminal prosecution, disciplinary actions from his or her professional licensing board, and civil liability due to the administration of the opioid antagonist.

Based on this statute, the Board would not require a pharmacist to comply with 20 CSR 2220-6.040 when administering naloxone in good faith to an overdosing patient.

F.23 EPINEPHRINE/ASTHMA MEDICATION

Section 167.630, RSMo, authorizes Missouri school districts to obtain prefilled epinephrine auto syringes by prescription. Section 167.635 contains the same allowance for asthma related rescue medications. To obtain prefilled epinephrine auto syringes or asthma related rescue medications, a prescription is required from a licensed physician, a physician's assistant, or nurse practitioner. The school district must be designated as the patient and the school nurse's name must be on the prescription. Pharmacies may legally dispense prescriptions that comply with § 167.630 or § 167.635.
Section 196.990, RSMo, also authorizes pharmacists to dispense epinephrine auto-injectors to an “authorized entity” based on a prescription issued by a Missouri licensed physician in the name of the authorized entity (e.g., Jefferson City Parks and Recreation). An “authorized entity” is defined as:

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.

Only a Missouri licensed physician may issue an epinephrine prescription to an authorized entity under § 196.990. The prescription may not be written by an advanced practice registered nurse or a physician assistant. Prescriptions for an authorized entity would be valid for 12-months and may be refilled as needed unless otherwise restricted by the prescriber. Quantity limits are as prescribed. The prescription must be maintained and documented in the same manner as other non-controlled prescriptions.

Section 196.990.4 contains mandatory training requirements for “expected auto-injector users” who may be administering or providing epinephrine to the public on behalf of an authorized entity. It appears the additional training requirements only apply to users that acquire epinephrine auto-injectors “under a prescription issued in accordance with” § 196.990. Pharmacists dispensing epinephrine from the pharmacy’s regular inventory do not have to complete additional training unless the medication was received based on a prescription issued to the pharmacy under § 196.990.

The Board has been asked if pharmacists can provide the required training for auto-injector users. The statute provides:

Expected epinephrine auto-injector users [must] 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.

Licensees should contact the Department of Health for additional questions on qualifying training.
G.1 GENERAL REQUIREMENTS

A Class D (Non-Sterile Compounding) pharmacy permit is required for pharmacies performing non-sterile compounding in batch quantities using bulk active ingredients. Rule [20 CSR 2220-2.400] defines compounding 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 also includes 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.*

The Board does not consider reconstituting or mixing ingredients for an FDA approved non-sterile drug product to be compounding (e.g., Benzaclin, Benzamycin, Epamid etc.). However, the use of compounding kits that include the compounding ingredients is considered compounding (e.g., CutisPharma First Kits). Licensees using compounding kits that include the compounding ingredients must comply with the Board’s compounding rules, including, completion of the compounding log.

Pharmacies may not compound products that have been withdrawn from the market due to safety.

- As defined by the Board’s rules, compounding does not include incorporating a flavoring agent. However, licensees should indicate that the product was flavored on the patient container and the added flavoring must be documented in the prescription record. Licensees may not flavor a prescription dispensed by another pharmacy. Flavoring an OTC product requires a prescription.

G.2 PRESCRIPTION REQUIREMENTS

Except as otherwise provided by law, pharmacists/pharmacies may only dispense compounded products pursuant to a prescription (or a medication order for Class-B pharmacies). Pharmacists/pharmacies may not offer compounded products to other pharmacies, practitioners or commercial entities for office use or for subsequent resale. [20 CSR 2220-2.400(12)] Pharmacies/pharmacists may, however, dispense a compounded product for a prescriber to administer in the prescriber’s office if a valid prescription or medication order has been received for the individual patient. Please consult BNDD/DEA if a controlled substance is involved.

Pharmacists/pharmacies may compound drugs in “limited quantities” prior to receiving a valid prescription if there is a history of receiving/filling valid prescriptions pursuant to an established relationship between the pharmacist, patient and prescriber. [20 CSR 2220-2.400(7)(C)]. For purposes of 20 CSR 2220-2.400, a “limited quantity” is defined as a three (3) month supply of a batched product or a one (1) year supply for compounded products intended for external use (e.g., creams, ointments, lotions or liniments). While advance preparation is allowed, a prescription is required for dispensing.

Compounding may only be done by prescription/medication order, regardless of the type of product (e.g., OTC, herbal). [20 CSR 2220-2.400(10)].

- Pharmacies/pharmacists are prohibited from compounding for office stock unless the pharmacy is licensed as a Missouri drug distributor and is registered with the FDA as a drug manufacturer or a 503(b) drug outsourcing facility.
G.3 COMMERCIALY AVAILABLE PRODUCTS

Pharmacists may not compound products that are commercially available or that are essentially copies of commercially available products. [20 CSR 2220-2.400(9)]. “Essentially copies” include different dosage forms (e.g., suspension vs. solution, tablet vs. capsule). Missouri law recognizes the following exemptions:

- A commercially available product may be compounded if the product is temporarily unavailable due to problems other than safety or effectiveness (e.g., shortage/back order). Licensees should document unavailability in the prescription record. [20 CSR 2220-2.400(9)]. The Board also recommends documenting the dates the product was unavailable and keeping any documentation from the manufacturer/distributor. Licensees must stop compounding the product once the commercially available product returns to the market.

- A commercially available product may be compounded if there is sufficient documentation of a specific medical need for the prescription/medication order. [20 CSR 2220-2.400(9)]. The “specific medical need” is the medical reason why the commercially available product cannot be used. Cost or convenience are insufficient reasons.

“Sufficient documentation” is considered to be either a prescription or medication order documenting the specific medical need or a notation in the pharmacy’s records that verbal or other documentation of the medical need was received for each prescription/medication order. Notations should include the name of the person verifying the medical need, the date, and the specific medical need/ reason given.

The Board does not consider compounding kits that include compounding ingredients to be commercially-available so a pharmacy may still compound these preparations without using the kit. However, if a specific compounding kit is prescribed, a pharmacist would need prescriber’s authorization to compound without using the kit.

G.4 PRODUCT VERIFICATION

The dispensing pharmacist must ensure compounded products are properly prepared, labeled, stored, dispensed and distributed. [20 CSR 2220-2.400(8)]. Before release, the pharmacist must visually inspect bulk drug substances and all finished products for container closure integrity, visible particulates or other foreign matter/visual defects.

For quality purposes, the dispensing pharmacist must also ensure that:

1) Each person assisting in compounding is capable and qualified to perform their assigned duties;

2) All ingredients have their expected identity, quality and purity;

3) Reasonable assurance exists that compounding processes/procedures are always carried out by pharmacy staff as intended or specified; and

4) Compounding conditions/procedures are adequate for preventing mix-ups or other errors.

☑️ The Board has observed several instances of pharmacists compounding with expired ingredients. In many instances, the expired date was recorded in the compounding log signed by the pharmacist. Pharmacists should review all log entries for accuracy. Proactive steps should be taken to identify and remove expired drugs and ingredients.

G.5 LABELING
In addition to other prescription labeling requirements, the actual name of each active or therapeutic ingredient contained in a compound must be listed on the patient’s prescription container or on an auxiliary label (e.g., labels that indicate only “magic mouthwash” are non-compliant.) [20 CSR 2220-2.400(7)(F)].

G.6 BEYOND-USE DATES

Batched compounded products must be assigned an in-house batch/lot number and a “beyond-use date” after which a compounded preparation should not be used. [20 CSR 2220-2.400(7)(A)6.] The beyond-use date must be determined from the date the preparation is compounded. Licensees should use their professional judgment in determining appropriate beyond-use dates. Because compounded products are intended for immediate administration or following short-term storage, beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products. [20 CSR 2220-2.400(4)]. Licensees may be asked to explain or support their rationale for assigning a beyond-use date.

Compounds that are not picked up by the patient and returned to stock are considered batched and must be assigned a batch number and a beyond-use date in the compound log and on the label.

G.7 INGREDIENTS/CONTAINERS [20 CSR 2220-2.400(6)]

Proper controls must be maintained over drug products/ingredients, containers and container closures to prevent contamination. Drug components must meet compendial standards (e.g., USP, NF). If non-compendial bulk drug substances are used, a certificate of analysis must be maintained on file. [20 CSR 2220-2.400(8)2.] Non-drug substances must be contaminant free and maintain full potency.

Container systems must be stored and used in a manner that will adequately protect against foreseeable deterioration or contamination. Drug products, ingredients, containers and container closures may not be reactive, additive or absorptive in any way that would alter the safety, identity, strength, quality or purity of the compounded product beyond the desired result.

Compounding materials must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration. Excess products must be labeled with the name of the drug(s), an in-house lot number and the beyond-use date and must be stored and accounted for under conditions dictated by their composition and stability. [20 CSR 2220-2.400(6)].

For bulk ingredients that do not bear an expiration date, the pharmacy is encouraged to contact the manufacturer to determine the actual expiration date. If one is not provided, the pharmacy is encouraged to have a procedure for establishing an in-house expiration date for the ingredient.

G.8 FACILITIES/EQUIPMENTS [20 CSR 2220-2.400(5)]

Compounding area(s) must be clean and sanitarily maintained at all times. Compounding areas must be free of infestation and trash must be disposed of in a timely manner.

Compounding equipment must be adequately and appropriately designed for the activities performed. Equipment surfaces may not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired. [20 CSR 2220-2.400(6)(E)]. Equipment must be appropriately located to allow for proper use, cleaning and maintenance. [20 CSR 2220-2.400(5)(C)].
If drugs with special contamination precautions are used (e.g., penicillin), appropriate measures must be utilized to prevent cross-contamination. [20 CSR 2220-2.400(5)(B)]. Appropriate measures may include, but may not be limited to, dedicating or adequately cleaning equipment.

**G.9 QUALITY CONTROL**

Pharmacies must establish and maintain appropriate quality control measures over compounding methods. [20 CSR 2220-2.400(7)] Quality control measures must include:

1. Methods for compounding to ensure finished products have the identity, strength, quality and purity they purport or are represented to possess, and;
2. A description of the compounding process and the order for adding drug products/ingredients, if applicable.

Additionally, pharmacies must develop and maintain an outcome related drug monitoring system for evaluating the quality of compounding services. At a minimum, the monitoring system must evaluate/track infection rates, adverse drug reactions, recalls and prescriber/client complaints.

**G.10 COMPOUNDING LOG**

Pharmacies must maintain a separate compounding log that includes [20 CSR 2220-2.400(7)(A)]:

1. The compounding method used;*
2. The compounding date;
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, if necessary for proper compounding, the order of drug product/ingredient addition (e.g., recipe/formula cards);*
6. 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. A prescription number or a readily retrievable unique identifier for the compound.

*This information may be stored separately in the pharmacy’s records, provided the records are immediately retrievable.

✔️ All prescriptions numbers/identifiers dispensed from a batch compound must be recorded individually on the compound log.

**G.11 RECALLS**

A recall must be initiated if a compounded product is deemed to be misbranded or adulterated. [20 CSR 2220-2.400(8)(C)]. In the event of a recall, the pharmacy must notify the prescriber of: 1) the nature of the recall, 2) the problem(s) identified and 3) any recommended action(s). If the compounded product could potentially cause patient harm, the same recall notification must be provided to the patient. Recall(s) must be reported to the Board in writing within three (3) business days.

✔️ Prescribers may be notified verbally or in writing. Licensees should exercise their professional judgment when determining notification methods. The Board recommends retaining proof of the date and manner of the recall/notification in the pharmacy’s records.

**G.12 ADVERTISING/SOLICITATION**
Licensees may advertise or provide information regarding the availability of compounding services and the type of compounding offered. However, licensees may not compare compounded products to commercially available products or make specific claims without supporting data (e.g., designating a product as slow release). [20 CSR 2220-2.400(12)]. Alternatively, licensees may not attempt to solicit business by making specific claims about compounded products without analytical data to support the claims for each product. Licensees must produce data for their specific product and may not rely on data obtained from other sources.
### H.1 STERILE COMPOUNDING

Class H Sterile Compounding pharmacies are required to comply with all applicable provisions of state/federal law, including rule 20 CSR 2220-2.200 governing sterile pharmaceuticals and 20 CSR 2220-2.400 which establishes standards of practice for all compounding pharmacies. See Section F. Compliance with 20 CSR 2220-2.200 and 20 CSR 2220-2.400 is mandatory for all pharmacies holding a Class H Sterile Compounding pharmacy permit even if the pharmacy is not currently providing sterile compounding services.

The Board has not adopted USP Chapter 797 at this time. USP Chapter 797 is currently under revision; the Board intends on reviewing Missouri’s regulations after USP Chapter 797 is finalized. Interested parties should monitor the Board’s website for additional information.

In August 2016, the Board issued an emergency sterile compounding that substantially revised its sterile compounding rule. Interested parties should review the Sterile Compounding Rule Implementation Guide for additional compliance information. The following major changes were included in the emergency sterile compounding rule and are summarized in the Implementation Guide:

- Compounding definitions (equipment and classified areas)
- Risk-level classifications
- Garbing requirements
- Training requirements
- Cleaning & disinfection requirements
- Media-fill testing
- Environmental monitoring
- End-preparation testing
- Remedial investigations/recalls

### H.2 COMPOUNDING RISK LEVELS

Rule 20 CSR 2220-2.200 establishes the following compounding risk levels:

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Emergency &amp; Amended Rule</th>
</tr>
</thead>
</table>
| Risk Level 1 | • Preparations stored at controlled room temperature and assigned a beyond-use date of 48 hours or less  
• Preparations stored under refrigeration and assigned a beyond-use date of 7 days or less  
• Preps stored frozen and assigned a beyond-use date of 30 days or less |
| Risk Level 2 | • Preparations stored at controlled room temperature and assigned a beyond-use date greater than 48 hours  
• Preparations stored under refrigeration and assigned a beyond-use date greater than 7 days  
• Preparations stored frozen and assigned a beyond-use greater than 30 days |
| Risk Level 3 | • Products compounded from nonsterile ingredients or compounding with nonsterile components, containers or equipment before terminal sterilization  
• Products prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization |
H.3 PRESCRIPTION REQUIREMENTS

As with non-sterile compounding, pharmacies may only dispense compounded sterile preparations pursuant to a patient specific prescription or lawful medication order. [20 CSR 2220-2.400]. Drugs may be compounded in “limited quantities” prior to receiving a valid prescription if there is a history of receiving/filling valid prescriptions pursuant to an established relationship between the pharmacist, patient and prescriber. [20 CSR 2220-2.400(7)(C)]. While products may be prepared in advance, a patient-specific prescription/medication order is required prior to dispensing.

For purposes of 20 CSR 2220-2.400, a “limited quantity” is defined as a three (3) month supply of a batched product or a one (1) year supply for compounded preparations intended for external use (e.g. creams, ointments, lotions or liniments).

H.4 COMPOUNDING FOR OFFICE USE

Pharmacies may not sell or dispense sterile compounds to practitioners or other prescribers for office use. [20 CSR 2220-2.400(1), (12)]. This includes hospitals, surgery centers, etc. Once again, a patient specific prescription/medication order is required prior to dispensing. Pharmacies/pharmacists may only compound for office use if the pharmacy/pharmacist is registered as an FDA drug manufacturer or a drug outsourcing facility.

Licensees distributing non-patient specific compounded preparations medication may also be required to register with the FDA as a section 503(b) drug outsourcer. 503(b) drug outsourcers are licensed by the Board as drug distributors. Licensees should consult with legal counsel to ensure compliance with state and federal law.

H.5 COMMERCIALY AVAILABLE PRODUCTS

Generally, Missouri law prohibits licensees from compounding preparations that are commercially available or that are essentially copies of commercially available products. “Essentially copies” includes different dosage forms (e.g., suspension vs. solution, tablet vs. capsule).

Licensees may only compound a commercially available product:

1) If the product is temporarily unavailable due to problems other than safety or effectiveness (e.g., on back order). Unavailability must be documented in the pharmacy’s records. [20 CSR 2220-2.400(9)]. The pharmacy must stop compounding the product once the product becomes available again; or

2) If a “specific medical need” for the prescription exists. [20 CSR 2220-2.400(9)]. The “specific medical need” is deemed to be the medical reason why the commercially available product cannot be used. The nature of the “specific medical need” must be documented on the prescription or otherwise in the pharmacy’s prescription records. [20 CSR 2220-2.400(9)]. Cost or convenience are insufficient to establish a “specific medical need.”

H.6 POLICIES & PROCEDURES

Pursuant to 20 CSR 2220-2.200(2), Class H Sterile Compounding pharmacies must maintain a policy and procedure manual that addresses all aspects of sterile compounding performed by the pharmacy. Policy & procedure manuals should be regularly reviewed and updated to ensure appropriate practices.
At a minimum, manuals must be reviewed annually. [20 CSR 2220-2.200(2)]. Policy and procedure manuals and documentation of the annual review will be required during inspection.

✔ Board inspectors continue to observe instances of incomplete or outdated policy and procedure manuals. In other cases, pharmacy staff have not been updated or trained on recent changes. Manuals should be accessible to and reviewed by all pharmacy staff, including, new hires. Staff should be retrained when substantive changes are made or when there is a breach in aseptic technique.

H.7 ADDITIONAL COMPLIANCE REQUIREMENTS

This section includes a general summary of selected rule provisions. Once again, licensees should review the Implementation Guide and rule 2 CSR 2220-2.200 in its entirety for full compliance information. Additional sterile compounding requirements exist that are not listed above, including, but not limited to, PEC/environmental certification, aseptic skills technique training/assessment, media-fill testing, environmental monitoring, recalls and remedial investigations).
**I.1 GENERAL REQUIREMENTS**

Pharmacies are required to designate a primary record keeping system that may either be a non-electronic (manual) system or an electronic system. [20 CSR 2220-2.010(2)]. All dispensing activities must be recorded in the designated system.

**I.2 NON-ELECTRONIC (MANUAL) PRESCRIPTION RECORD SYSTEM**

If a non-electronic record system is used, the pharmacy must maintain the following:

- A separate prescription file for Schedule I and II controlled substance prescriptions;
- A separate prescription file for Schedule III, IV and V controlled substance prescriptions; and
- A separate file for all other non-controlled drug prescriptions. [20 CSR 2220-2.010(3)-(4)]

The following information must be maintained in a non-electronic system for each original and refilled prescription:

- The date the prescription was prescribed and the date of initial dispensing, if different;
- A sequential prescription label number or other unique identifier;
- The name of the patient(s), or if an animal, species and owner’s name;
- The prescriber’s name for oral prescriptions or signature for written or faxed prescriptions. *Electronic signatures must comply with all applicable provisions of 20 CSR 2220-2.085*;
- For controlleds, the address of the prescriber and the patient and the prescriber’s DEA number;
- Name, strength and dosage of drug, device or poison dispensed and the directions for use;
- The number of refills authorized;
- The quantity dispensed in weight, volume, or number of units;
- The date of refill, if any;
- The identity of the pharmacist responsible for reviewing the accuracy of data on each original prescription;
- The identity of the pharmacist responsible for verifying the final product prior to dispensing on each original and refill prescription, if different;
- Whether generic substitution has been authorized by the prescriber;
- Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug, and;
- If additional refills are authorized and added to the prescription, a notation indicating the method and source of the authorization must be a part of the manual record or hard copy. The expiration date of the original prescription must remain the same.

✔ The identity of the pharmacist verifying prescription data and the pharmacist verifying the final product must be recorded, if different.

Pharmacies maintaining a non-electronic (manual) system must also record the following on the reverse side of the prescription for each refill:

- The date the drug, medicine or poison was dispensed;
- The dispensing pharmacist’s initials; and
- The amount of drug dispensed to the patient, if different from the face of the prescription. [20 CSR 2220-2.010(3)]

Prescriptions must be filed by the prescription number/unique identifier. [20 CSR 2220-2.010(2); 20 CSR 2220-2.017].
1.3 ELECTRONIC PRESCRIPTION RECORD SYSTEMS [20 CSR 2220-2.080]

If an electronic prescription record is designated, the system must allow for the separate identification/retrieval of Schedule I and II controlled substance prescriptions, the separate identification/retrieval of Schedule III-V controlled substance prescriptions and the separate identification/retrieval of other non-controlled prescriptions. Required prescription hard copies must be stored in a three-file system as listed in section H.2.

Electronic record systems must be able to store and retrieve the following for each original and refill prescription:

1) A unique, sequential prescription label number;
2) If applicable, a unique readily retrievable identifier;
3) Date the prescription was prescribed;
4) The date the prescription was initially filled and the date of each refill;
5) Patient’s full name, or if an animal, the species and owner’s name;
6) The patient’s address or animal owner’s address, if a controlled substance has been prescribed;
7) The prescriber’s full name.
8) For controlled substances, the prescribers address and DEA #;
9) Name, strength and dosage of drug, device or poison dispensed and any directions for use;
10) Quantity originally dispensed;
11) Quantity dispensed on each refill;
12) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
13) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;
14) The number of authorized refills and quantity remaining;
15) Whether generic substitution has been authorized by the prescriber;
16) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and
17) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or substitution authority. If additional refills are authorized, the EDP system must indicate the method and source of authorization. [20 CSR 2220-2.080(2)]

Information may be entered into the EDP system by a licensed pharmacist or a pharmacy technician or intern pharmacist working under the pharmacist’s direct supervision. [20 CSR 2220-2.080(1)]. However, the pharmacist is personally responsible for the accuracy of information inputted. [20 CSR 2220-2.080(1)].

Production of Records: An EDP system must be capable of retrieving records within two (2) hours of a request by a Board inspector. Alternatively, the pharmacy must provide a computer terminal that will allow the inspector to immediately access the system. An inspector may ask for code/login information to access records [20 CSR 2220-2.080(7)].

Drug Utilization: EDP systems must be able to retrieve a drug utilization listing for any drug for the previous twenty-four (24) months. Information must be available by specific drug product, patient name or practitioner. Drug utilization reports must be provided within three (3) working days of a Board request. [20 CSR 2220-2.080(12)].
In 2013, the Board removed the requirement that a pharmacist maintain a bound logbook or separate file (a.k.a. the “pharmacist signature log”) signed daily by the pharmacist to verify that prescription information was accurately entered. Instead, the pharmacy’s electronic prescription record must now identify the pharmacist responsible for verifying the accuracy of prescription data on each original prescription. Federal law still requires licensees to maintain a logbook or a signed printout for verifying controlled substance refill data. [See 21 CFR 1306.22(f)(3)]

I.4 PRESCRIPTION HARD COPIES

Section 338.100, RSMo, requires that the “original or order” of each drug must be maintained by the pharmacy for at least five (5) years. Accordingly, a hard copy of each prescription must be maintained by the pharmacy regardless of source (faxed or electronic). For prescriptions received electronically, a hard copy of the prescription must be printed and maintained in the pharmacy’s records unless the pharmacy has an electronic record-keeping system as described in Section H. Prescriptions must be filed by the consecutive number or the unique identifier. Note: The hard copy requirements also apply to controlled substances. A hard copy of an electronically prescribed controlled substance must be printed unless the pharmacy has an electronic record-keeping system that maintains a digital image of what was received.

I.5 ELECTRONIC RECORD KEEPING SYSTEMS (ERS)

In lieu of a physical prescription hard copy, pharmacies that have an electronic record keeping system that complies with § 338.100, RSMo, may maintain a digitized image (scan) of a prescription. Rule 20 CSR 2220-2.083 defines an electronic record keeping system, or “ERS”, as a system that provides “input, storage, processing, communications, output and control functions for digitized images of original prescriptions.”

An electronic prescription record is different from an electronic record keeping system. To qualify as an ERS, the pharmacy’s system must be able to capture “an exact digitized image” (scanned image) of the actual prescription, including, the reverse side of the prescription, if applicable. Simply transferring or electronically recording prescription data is insufficient. Pharmacies that do not have a compliant ERS must still maintain a physical prescription hard copy.

Digitized prescription images in an ERS must be readily retrievable and capable of being provided or reviewed immediately or within (2) hours of a request from the Board or a Board inspector. To prevent loss, digitized images in the ERS must be stored, copied or saved onto secure storage media on a regular basis. Pharmacies with an ERS must maintain a written policy and procedure manual that includes policies/procedures for reviewing compliance.

I.6 CONFIDENTIALITY

Patient records must be confidentially maintained in compliance with HIPAA and all state and federal law. Licensees have a duty to properly safeguard confidential records. The Board is aware that records may be reviewed by third-party entities conducting audit/review functions (e.g., pharmacy benefit managers, private consultants). Confidential records that do not relate to a third-party inquiry must be securely maintained to avoid unauthorized access/disclosure.

Pharmacies should exercise caution in discarding or destroying drug containers. Patient specific information should be removed before placing the container in the trash or giving the container to a reverse distributor.
### 1.7 RECORD RETENTION

*(This chart includes select record keeping requirements and is not a complete listing. Licensees should review all relevant laws to ensure record keeping compliance.)*

<table>
<thead>
<tr>
<th><strong>PHARMACIST</strong></th>
<th><strong>PHARMACY</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Continuing Education</strong></td>
<td>Must be retained for two (2) reporting periods immediately prior to renewal</td>
</tr>
<tr>
<td><strong>Audit of Class-I Consultant Pharmacy Records</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Compounding Log</strong></td>
<td>2 Years</td>
</tr>
<tr>
<td><strong>Compounding Records</strong></td>
<td>2 Years</td>
</tr>
<tr>
<td><strong>Controlled Substance Prescription Orders</strong></td>
<td>5 years</td>
</tr>
<tr>
<td><strong>Controlled Substance Transfer Records/DEA 222 forms</strong></td>
<td>2 Years</td>
</tr>
<tr>
<td><strong>Controlled Substance Inventories</strong></td>
<td>2 Years</td>
</tr>
<tr>
<td><strong>Distribution Records</strong></td>
<td>2 Years</td>
</tr>
<tr>
<td><strong>Drug Invoices</strong></td>
<td>2 Years</td>
</tr>
<tr>
<td><strong>Immunization/Medication Administration Records</strong></td>
<td>2-Years</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Immunization Protocol</strong></td>
<td>8 Years after termination</td>
</tr>
<tr>
<td><strong>Medication Therapy Services (MTS) Protocol</strong></td>
<td>7 Years</td>
</tr>
<tr>
<td><strong>MTS Patient Records (generally)</strong></td>
<td>7 Years</td>
</tr>
<tr>
<td><strong>Prescription Orders</strong></td>
<td>5 Years</td>
</tr>
<tr>
<td><strong>Sterile Compounding Records</strong></td>
<td>2 Years</td>
</tr>
</tbody>
</table>
J.1 GENERAL REQUIREMENTS

Section 338.010, RSMo, authorizes a pharmacist to administer the following vaccines pursuant to a written protocol with a Missouri licensed physician: influenza, shingles, meningitis, pneumonia, hepatitis A, hepatitis B, tetanus, diphtheria and pertussis *(This includes combination products with the authorized vaccines such as Tdap).* Licensees immunizing by protocol must comply with:

- All state and federal laws governing vaccine information statements and informed consent;
- Manufacturer guidelines, and;
- All applicable Centers for Disease Control (CDC) guidelines. Compliance with CDC guidelines is mandatory even if manufacturer recommendations are different.

Patients must be at least 12 years old. Vaccinations may only be delegated to qualified intern pharmacists as described below.

After immunizing, patients must be asked to remain in the pharmacy a “safe amount of time” to observe any adverse reactions. *§ 338.010.12(2).* “Safe amount of time” is not defined in statute. Pending further rulemaking, pharmacists should use their professional discretion when determining the time needed to adequately assess adverse reactions. The Board recommends documenting when a patient refuses to stay.

J.2 IMMUNIZATION QUALIFICATIONS

Section 338.010, RSMo, and 20 CSR 2220-6.050 establishes the following requirements for pharmacists immunizing by protocol:

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Immunization By Protocol Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✓ Active Missouri RPh license</td>
</tr>
<tr>
<td></td>
<td>✓ Notification of Intent filed with Board <em>(must be filed online prior to immunizing)</em></td>
</tr>
<tr>
<td></td>
<td>✓ Current CPR certification from the American Heart Association, American Red Cross or an equivalent body</td>
</tr>
<tr>
<td></td>
<td>✓ Completion of vaccine administration certificate program accredited by ACPE or an entity approved by the Board</td>
</tr>
<tr>
<td></td>
<td>✓ Protocol with a Missouri licensed physician</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Notification Renewal</th>
<th>Immunization By Protocol Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✓ Notification of Intent filed annually with the Board <em>(must be filed online)</em></td>
</tr>
<tr>
<td></td>
<td>✓ Current CPR certification</td>
</tr>
<tr>
<td></td>
<td>✓ Two (2) CE hours (0.2 CEU) related to administration of vaccinations within the prior twelve (12) months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Missouri Licensed Intern Pharmacists</th>
<th>MAY IMMUNIZE IF THE INTERN:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✓ Has a current and active CPR certification</td>
</tr>
<tr>
<td></td>
<td>✓ Has completed an immunization certificate program accredited by ACPE or an entity approved by the Board</td>
</tr>
<tr>
<td></td>
<td>✓ Is under the direct supervision of a pharmacist qualified to immunize</td>
</tr>
</tbody>
</table>

✓ *Section 338.100.12* requires that pharmacists administering vaccines display a certificate showing that he/she has met all immunization training requirements. The Board does not issue a separate immunization certificate/license. Instead, licensees should print and display their online license verification from the Board’s website which will show if a Notification of Intent has been filed. Online license verifications can be retrieved by searching the licensee’s name at [https://renew.pr.mo.gov/pharmacy-licensee-search.asp](https://renew.pr.mo.gov/pharmacy-licensee-search.asp). Posting an immunization training certificate does not meet the statutory requirement.
J.3 PROTOCOL REQUIREMENTS

To immunize, pharmacists must have a written protocol with a Missouri-licensed physician who is actively engaged in the practice of medicine. [20 CSR 2220-6.050(6)]. The authorizing physician’s practice location must be no further than fifty (50) miles by road from the pharmacist, using the most direct route available. Protocols must include:

1. The identity and signature of the participating pharmacist and physician;
2. The time period of the protocol;
3. The vaccines which may be administered;
4. The identity of the patient or groups of patients who may be vaccinated;
5. The authorized routes and anatomic sites of administration;
6. Provisions for creating a prescription for each administration under the authorizing physician’s name;
7. A course of action for addressing emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. The length of time the pharmacist is required to observe a patient for adverse events following an injection;
9. Provisions for disposing of used and contaminated supplies;
10. The street addresses of the pharmacy or other locations where vaccines may be administered;
11. Record keeping requirements and procedures for notification of administration; and
12. Provisions for terminating the protocol at the request of any party at any time.

Immunization protocols may be valid for no longer than one (1) year; a new protocol must be signed each year. Protocols must be maintained for at least eight (8) years after the protocol is terminated.

Protocol Amendments: Amendments to the protocol must be signed and dated by all participating pharmacists and prescribers. Signatures may be included on the original protocol or on a separate document that is attached to the protocol. Pharmacists may be added to an existing protocol if the protocol is signed by both the newly added pharmacist and the authorizing physician(s).

The Board has observed multiple instances where the protocol did not include each location where a pharmacist immunizes as a relief or “floater” pharmacist. Licensees should check their protocols to make sure each immunization location is listed before immunizing.

J.4 PRESCRIPTION REQUIREMENTS

Within seventy-two hours (72) hours after administering a vaccine by protocol, the pharmacist must either obtain a prescription from the authorizing physician for the vaccine or create a prescription under the protocol physician’s name documenting the dispensing. [20 CSR 2220-6.050(7)(B)]. The protocol physician must be listed as the prescriber and not the pharmacist/intern pharmacist.

J.5 NOTIFICATION REQUIREMENTS

Licensees must comply with the following notification requirements [20 CSR 2220-6.050(8)]:

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Notification Requirements</th>
<th>Notification Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorizing Protocol Physician</td>
<td>Within 72 hours after administration</td>
<td>✓ The identity of the patient&lt;br/&gt;✓ The vaccine(s) administered&lt;br/&gt;✓ The route of administration&lt;br/&gt;✓ The anatomic site of administration</td>
</tr>
</tbody>
</table>
## SECTION I: IMMUNIZATION BY PROTOCOL

<table>
<thead>
<tr>
<th>Primary Care Provider (If different from the authorizing physician)</th>
<th>Within fourteen (14) days of administration. * Notification dates should be documented in the patient’s record.</th>
<th>Same notification as authorizing physician</th>
<th>Must be in writing. May be transmitted electronically or by fax/mail. Documentation of notification required.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Events</td>
<td>Within twenty-four (24) hours after learning of the adverse event/reaction</td>
<td>The authorizing physician must be notified and the patient’s primary care provider, if different. Notification must include a description of the adverse event/reaction and any other requirements mandated by protocol.</td>
<td>In the pharmacist’s discretion unless defined in the protocol. However, documentation of the notification must be maintained.</td>
</tr>
<tr>
<td>State/Federal Entities</td>
<td>As required by law</td>
<td>As required by law</td>
<td>As required by law</td>
</tr>
</tbody>
</table>

A good faith attempt should be made to collect PCP information (e.g., verbally or on the immunization authorization form). PCP notification is only required if the PCP’s information is known. The Board suggests documenting if a patient does not provide PCP information.

### J.6 RECORDS [20 CSR 2220-6.050(7)]

Pharmacists administering vaccines by protocol must document and maintain a record of:

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 name or identifiable initials of the administering pharmacist; and
6. Any adverse reaction and who was notified, if applicable.

Vaccination records must be maintained for at least two (2) years. If vaccines are administered on behalf of a pharmacy, records must be maintained at the pharmacy. If the vaccine is not administered on behalf of a pharmacy, records should be maintained at an address identified in the protocol.

✔️ For additional immunization compliance information, see the Board’s Immunization Checklist online at [http://pr.mo.gov/boards/pharmacy/13863/1].pdf.
K.1 AUTHORIZED ACTIVITY

Pharmacists may administer medications or vaccines pursuant to a medical prescription order subject to the requirements below. [20 CSR 2220-6.040].

<table>
<thead>
<tr>
<th>Administration Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualification Requirements</td>
</tr>
<tr>
<td>✓ Notification of Intent filed with Board (Notifications must be filed online)</td>
</tr>
<tr>
<td>✓ Active Missouri RPh license</td>
</tr>
<tr>
<td>✓ Current CPR certification from the American Heart Association, American Red Cross or an equivalent body</td>
</tr>
<tr>
<td>✓ Completion of drug administration certificate program accredited by ACPE or an entity approved by the Board</td>
</tr>
<tr>
<td>✓ A written policy and procedure manual covering all aspects of drug administration, including the disposal of used/contaminated supplies and handling of acute adverse events. Manuals must be annually reviewed and available for inspection.</td>
</tr>
<tr>
<td>Notification Renewal</td>
</tr>
<tr>
<td>✓ Notification of Intent filed annually with the Board (Notifications must be filed online)</td>
</tr>
<tr>
<td>✓ Current CPR certification</td>
</tr>
<tr>
<td>✓ Two (2) CE hours (0.2 CEU) related to drug administration within the prior twelve (12) months</td>
</tr>
<tr>
<td>Additional Compliance Requirements</td>
</tr>
<tr>
<td>✓ Pharmacist must comply with all state and federal laws governing patient information statements and informed consent</td>
</tr>
<tr>
<td>Missouri Licensed Intern Pharmacist</td>
</tr>
<tr>
<td>May administer if the intern:</td>
</tr>
<tr>
<td>✓ Has a current and active CPR certification</td>
</tr>
<tr>
<td>✓ Completed an administration certificate program accredited by ACPE or an entity approved by the Board</td>
</tr>
<tr>
<td>✓ Interns must be under the direct supervision of a pharmacist qualified to administer drugs</td>
</tr>
<tr>
<td>Authorized Medication/Vaccines</td>
</tr>
<tr>
<td>As prescribed</td>
</tr>
</tbody>
</table>

Except as provided for intern pharmacists, medication administration may not be delegated.

K.2 PRESCRIPTION REQUIREMENTS

To administer medication, the prescription must contain:

1) The prescriber’s name;
2) The patient’s name;
3) The name of the drug and dose to be administered;
4) The route of administration;
5) The date of the original order;
6) The date or schedule, if any, of each subsequent administration; and
7) A statement that the drug is to be administered by a pharmacist. [20 CSR 2220-6.040(4)]

Board inspectors routinely observe prescriptions that are missing the prescribed route of administration and/or the statement that the drug is to be administered by a pharmacist. Prescriptions missing this information are not valid for administration. However, pharmacists may contact the prescriber for authorization to add these items; authorization should be documented in the pharmacy’s records.

K.3 RECORDS
The following records must be maintained for each administration:

1) The patient’s name, address, and date of birth;
2) The date, route, and anatomic site of administration;
3) The name, dose, manufacturer, lot number, and expiration date of the drug;
4) The name and address of the patient’s primary health care provider, as identified by the patient;
5) The name or identifiable initials of the administering pharmacist; and
6) The nature of any adverse reaction and who was notified, if applicable.  [20 CSR 2220-6.040(6)]

Records must be maintained separately from the pharmacy’s prescription records for a minimum of two (2) years.

**K.4 REPORTING/NOTIFICATIONS [20 CSR 2220-6.040(7)]**

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Notification Requirements</th>
<th>Notification Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prescriber</strong></td>
<td>Within 72 hours after administration</td>
<td>✓ The identity of the patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>✓ The name of the drug administered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>✓ The route of administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>✓ The anatomic site of administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>✓ The dose administered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>✓ The date of administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Notification must be documented in the pharmacy’s records</td>
</tr>
<tr>
<td><strong>Primary Care Provider</strong></td>
<td>Within fourteen (14) days of administration</td>
<td>Same notification as authorizing physician</td>
</tr>
<tr>
<td><em>(If different from the authorizing physician)</em></td>
<td></td>
<td>Must be in writing. May be transmitted electronically or by fax/mail. Documentation of notification required.</td>
</tr>
<tr>
<td><strong>Adverse Events</strong></td>
<td>Within twenty-four (24) hours after learning of the adverse event/reaction</td>
<td>The prescriber must be notified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Notification must be documented in the pharmacy’s records</td>
</tr>
<tr>
<td><strong>State/Federal Entities</strong></td>
<td>As required by law</td>
<td>As required by law</td>
</tr>
</tbody>
</table>

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L.1 GENERAL REQUIREMENTS

Pursuant to § 338.010, a Missouri licensed pharmacist may perform “medication therapy services” after obtaining a certificate of medication therapeutic plan authority from the Board. “Medication therapy services” are defined as:

[T]he designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient’s medication therapy or device usage pursuant to a medication therapy protocol. 20 CSR 2220-6.060(1)(F)

Medication therapy services (“MTS”) are different from “medication therapy management.” As commonly defined, medication therapy management includes a group of pharmacist provided services designed to optimize patient therapeutic outcomes. Medication therapy management is within the scope of the practice of pharmacy and can be performed by any Missouri licensed pharmacist (e.g., Medicare Part D medication therapy management). A MTS certificate is only required if a pharmacist is engaged in or has authority to initiate or modify drug/device therapy (e.g., Coumadin/Vancomycin dosing).

Modification of drug therapy includes, but is not limited to:
- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different or additional strength, dose, dosage form or dosage schedule; or
- Selecting, adding or changing a new or different route of administration.

Modification does not include dispensing a drug/device pursuant to a valid prescription from an authorized prescriber or generic substitution as authorized by § 338.056. Additionally, “medication therapy services” do not include administering medication by prescription order pursuant to 20 CSR 2220-6.040 or administering vaccines by protocol pursuant to 20 CSR 2220-6.050.

Prior to performing MT services, a pharmacist must have:
- A MTS certificate issued by the Board, and;
- A protocol with a Missouri licensed physician who is actively practicing medicine in Missouri. (See K.4- Protocol Requirements below).

All pharmacists performing MT services in Missouri are required to have a MTS certificate issued by the Board, including, pharmacists practicing in a hospital. For detailed information on obtaining a MTS certificate, see 20 CSR 2220-6.070 and the Board’s Medication Therapy Services Q&A.

L.2 SCOPE OF AUTHORITY

Licensees holding a current MTS certificate may perform medication therapy services as authorized by their governing protocol. However, the following restrictions/prohibitions apply:
- Pharmacists may not initiate or modify any controlled substance.
- Pharmacists may not independently prescribe. Instead, medication may only be modified or initiated as authorized by a written protocol with a Missouri physician.
- MT services may not be delegated. Pharmacy technicians and intern pharmacists may assist in providing MT services under the supervision of a pharmacist. However, technicians and interns may not initiate or modify drug therapy or perform any act that requires the professional judgment of a pharmacist.
L.3 CONTINUING EDUCATION

MTS certificate holders are required to complete 6 hours of CE in courses/programs related to medication therapy management each pharmacist biennial renewal period. The required CE may be used to satisfy Missouri’s biennial pharmacist CE requirements.

The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an “01” Drug Therapy Related ACPE universal activity number (Example: ACPE Universal Activity Number: xxxx-xxxx-xx-xxx-x01-x).

L.4 PROTOCOL REQUIREMENTS

Prior to performing MT services, pharmacists must have a written protocol with a Missouri licensed physician who is actively practicing medicine in the state of Missouri and whose practice location is no more than fifty (50) miles by road from the pharmacist.

The Board does not have a form or recommended protocol. However, protocols should clearly delineate the pharmacist’s scope of authority. As detailed in 20 CSR 2220-6.080(4), protocols must include:

- The names and signatures of the participating physician(s) and pharmacists(s);
- The effective date of the protocol;
- A description of MT services the pharmacist is authorized to provide. Authorized MT services must be within the skill, education, training and competence of the authorizing physician and pharmacist;
- A list of clinical conditions, diagnoses and diseases included in the written protocol and the type of medication therapy allowed in each case;
- The specific drugs or drug categories included in the protocol;
- A statement of the methods, procedures, decision criteria and plan the pharmacist is to follow when providing MT services;
- A description of any authority granted to the pharmacist to administer medication;
- A list of drugs the pharmacist is authorized to administer;
- A description of drug therapy related patient assessment procedures or testing the pharmacist may order or perform;
- Procedures for documenting the pharmacist’s MT decisions;
- Procedures and requirements for communicating and reporting MT decisions to the authorizing physician;
- Criteria for timely communication between the pharmacist and authorizing physician;
- A statement prohibiting the pharmacist from delegating the responsibility of MT services;
- Methods for physician review of MT activities;
- Provisions allowing the authorizing physician to access patient records;
- Mechanisms and procedures that allow the authorizing physician to override, rescind or otherwise modify the protocol;
- Emergency response procedures the pharmacist is authorized to follow to address emergency situations, including, anaphylactic or other adverse medication reactions, adverse needle sticks or other adverse events;
- All notification requirements required by 20 CSR 2220-6.080(5) (see K.8); and
- An address where required records will be maintained.
Protocols must be signed and dated by both the authorizing physician and pharmacist. If a protocol includes multiple physicians and pharmacists, a separate protocol is not required for each participating physician/pharmacist if all authorizing physicians and pharmacists sign and date a statement agreeing to be governed by the terms of the protocol.

Alternatively, MT services may be provided pursuant to a protocol approved by the “medical staff committee” of a hospital or hospital system. A “medical staff committee” is defined as the “committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management” (e.g., Pharmacy & Therapeutics Committee). Protocols approved by a medical staff committee can only be used to provide MT services to “individuals receiving medical diagnosis, treatment, or care at a hospital or a hospital clinic or facility.” A physician protocol is required for all other services.

Modifications/amendments to the protocol must be documented in writing and signed and dated by both the pharmacist and the authorizing physician prior to being implemented. Protocols may be rescinded by the authorizing physician or pharmacist with or without cause, provided the rescission is documented in writing.

Protocols must be reviewed and signed annually by the authorizing physician and pharmacist. The annual review date must be documented on the written protocol.

Protocols do not have to be filed with the Board but must be available if requested. Additionally, both the pharmacist and authorizing physician must retain signed copies of the written protocol for 8 years after the protocol is terminated.

### L.5 PHARMACY RESIDENTS

In lieu of an individual protocol, a pharmacy resident may perform MT services under the written protocol of another Missouri pharmacist if:

- The resident holds a MT certificate from the Board;
- The resident is enrolled in a residency training accredited by the American Society of Health System Pharmacists (ASHP) or that has a valid ASHP accreditation application pending, and;
- The resident is providing MT services under the supervision of a Missouri pharmacist with a current Board MT certificate.

### L.6 PRESCRIPTION ORDERS

To provide MT services, a pharmacist must obtain a prescription order from their protocol physician authorizing the pharmacist to perform MT services for a specific patient. Prescription orders for MT services are valid for no more than one (1) year and may be transmitted verbally, electronically or in writing.

Pursuant to 20 CSR 2220-6.080(2)(A), the prescription order must include:

- The patient’s name, address and date of birth;
- The date the prescription order was issued;
- The clinical indication for MT services (e.g., the patient’s diagnosis or disease);
- The authorizing physician’s name and address; and
- The length of time for providing MT services, if less than one (1) year.
Prescription orders for MT services must be in 2-line format as required by § 338.056 and must be maintained in the patient’s record (see K.6 below). Prescription orders maintained in compliance with 20 CSR 2220-6.080(2) will be deemed to comply with the general prescription requirements of 20 CSR 2220-2.018.

L.7 DOCUMENTATION OF SERVICES

Pharmacists must document and maintain an adequate patient record of MT services provided for each patient. At a minimum, the patient record must include:

- The patient’s name, birthdate, address and telephone number;
- The dates of any patient visits/consultations and the reason for the visit/consultation;
- Any pertinent assessments, observations or findings;
- Any diagnostic testing recommended or performed;
- The name of any medication or device modified;
- The strength, dose, dosage schedule or route of administration of any medication modified or administered;
- Referrals to the authorizing physician;
- Referrals for emergency care;
- Any contact with the authorizing physician concerning the patient’s treatment or MT services plan;
- Any informed consent for procedures, medications or devices;
- Any changes/alterations made to the prescription order based on contact with the prescriber; and
- Any consultation with other treatment providers for the patient and the results of the consultation.

L.8 THERAPY MODIFICATIONS

Pharmacists with a MTS certificate may modify drug therapy or device usage as provided in the governing protocol. Pharmacists may only modify non-controlled medications; controlled substances may not be modified by a pharmacist. [20 CSR 2220-6.080(6)(B)]. If the modification results in a drug/device being dispensed, the modification must be documented by creating a prescription in the pharmacy’s prescription records under the name of the authorizing physician. [20 CSR 2220-6.080(6)(A)]. All therapy modifications must be documented in the patient’s record.

- **Prescriptions generated by a pharmacist under 20 CSR 2220-6.080(6)(A) in the protocol physician’s name may be dispensed by any licensed pharmacy. However, pharmacists may not sign their name or the physician’s name to a written prescription generated under 20 CSR 2220-6.080(6). Instead, modifications may be verbally submitted to the other pharmacy or e-prescribed under the protocol physician’s name in accordance with governing law and protocol.**

L.9 NOTIFICATIONS

Pharmacists are required to provide the following notifications [20 CSR 2220-6.080(5)]:

<table>
<thead>
<tr>
<th>TYPE</th>
<th>RECIPIENT</th>
<th>TIMEFRAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylactic or adverse medication reactions, adverse needle sticks or other adverse events</td>
<td>Authorizing physician or physician’s authorized designee</td>
<td>24 Hours</td>
</tr>
<tr>
<td>Therapy modifications</td>
<td>Authorizing physician or physician’s authorized designee</td>
<td>24 Hours</td>
</tr>
</tbody>
</table>
Notifications must be in writing unless otherwise authorized by protocol. Pharmacists providing MT services for, or on behalf of, a health care entity may satisfy the notification requirements if the notification is recorded in a patient medical record that the health care entity is required to maintain under state or federal law (e.g., an EMR). Note: Protocols may include more stringent notification requirements.

L.10 RECORDS

The following records must be maintained under 20 CSR 2220-6.080:

<table>
<thead>
<tr>
<th>TYPE</th>
<th>TIMEFRAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient records required by 20 CSR 2220-6.080(7)</td>
<td>7 years after termination of protocol</td>
</tr>
<tr>
<td>Protocols, including, protocol changes or amendments</td>
<td>8 years after termination of protocol</td>
</tr>
<tr>
<td>Prescription orders for MT services</td>
<td>7 years after termination of protocol</td>
</tr>
<tr>
<td>Other records required by protocol</td>
<td>As governed by protocol</td>
</tr>
</tbody>
</table>

Records may be maintained electronically provided the record can be retrieved/reviewed on request. Records maintained at a pharmacy must be produced during an inspection or investigation. Records not maintained at a pharmacy must be produced within three (3) business days.
M.1 REGISTRATION REQUIREMENTS

All pharmacy technicians must be registered with the Board. [§ 338.013, 20 CSR 2220-2.700]. A pharmacy technician is defined as:

1. Any person who assumes a supportive role or who is utilized to “perform routine functions. . .in connection with the receiving, preparing, compounding, distributing or dispensing of medication.” [20 CSR 2220-2.700], or
2. “Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis.”

To be registered, an applicant must submit an application with the applicable fee and undergo a criminal history background check. Missouri does not currently impose minimum education or certification requirements for technician registration. However, technicians should be appropriately trained to perform the tasks delegated. Note: Additional training is required for sterile compounding. [20 CSR 2220-2.200(3)].

Applicants may begin working as a pharmacy technician once a completed registration application has been mailed to the Board. To be complete, the application must include an official fingerprint receipt and the required fee. A copy of the application must be maintained at the pharmacy. [§ 338.013]. The Board also recommends maintaining proof of mailing.

Pharmacies must maintain a current list of all pharmacy technicians authorized to access the pharmacy and their duties, as well as a policy and procedure manual for technician supervision. [20 CSR 2220-2.090(2)(BB), (CC)].

✓ Prescription delivery staff that solely perform delivery functions do not have to be registered as technicians. However, technician registration may be required if additional functions are performed.

✓ The pharmacist-in-charge is responsible for determining if an individual routinely has “independent access” to drug stock. The Board has determined that the ability to access the pharmacy does not automatically require technician registration (e.g., an employee/auditor has a key to the pharmacy). However, individuals who routinely use their access to independently enter the pharmacy must be registered.

M.2 SUPERVISION/ALLOWED ACTIVITIES

A pharmacy technician may assist in any area of pharmacy practice, including, receiving, preparing, compounding or dispensing prescriptions. [20 CSR 2220-2.700(1)]. However, technicians may not work independently and must be under the “direct supervision and responsibility” of a Missouri-licensed pharmacist at all times. [20 CSR 2220-2.700]. All prescriptions prepared or compounded by a technician must be finally verified/checked by a pharmacist, including, reconstituted products.

Technicians may not perform any activity that requires the “professional judgment” of a pharmacist. [20 CSR 2220-2.700(1)]. Prohibited activities include, but are not limited to:

- Final verification of a prescription before dispensing;
- Receiving or providing refill transfer information for controlled substance prescriptions [20 CSR 2220-2.120(1)(D)];
- Drug utilization review; and
- Patient counseling.

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The Board has determined that technicians may accept written prescriptions from patients for dispensing when no pharmacist is on duty. [20 CSR 2220-2.010(1)(B)]. However, technicians cannot take verbal prescription orders or count, fill, compound or enter a prescription if the pharmacist is absent. Technicians cannot come in early to process prescriptions before a pharmacist arrives or hand out or dispense prescriptions when no pharmacist is on duty, even if the prescription was previously checked by a pharmacist.

M.3 RENEWALS

Technician registrations are valid for one (1) year and expire annually on May 31st. A technician may not work if his/her registration is not renewed by May 31st. [§ 338.013.5]. Technicians who fail to renew by May 31st may submit a late renewal application until June 30th. Although the Board will accept the renewal application, the individual cannot work after May 31st until his/her registration has been renewed by the Board. Applicants wishing to renew after June 30th will be required to submit a new technician registration application and undergo a new criminal history background check.

Registration status may be checked on the Board’s website at https://renew.pr.mo.gov/pharmacy-licensee-search.asp. Practicing without a valid registration and/or allowing unlicensed practice constitutes grounds for discipline. [§ 338.055.2(10)].

M.4 MANDATORY REPORTING OF TECHNICIAN DISCIPLINE [§ 338.013.10]

Hospitals and licensed pharmacies are required to report to the Board any final disciplinary action taken against a technician for conduct that may constitute grounds for discipline under § 338.055. This requirement applies to any form of final disciplinary action, including, but not limited to, probation, suspension, demotion or reassignment. Pharmacies must also report any technician who voluntary resigns if a complaint or report has been made against the technician which could have led to final disciplinary action and the actions alleged in the complaint/report are cause for discipline under § 338.055. (See A-4 Mandatory Reporting of Discipline/Adverse Actions for more information.)

Notification of technician actions must be filed with the Board in writing within fifteen (15) days after the action. [20 CSR 2220-2.010(1)(P)] and must include:

- The name and permit number of the pharmacy;
- The name of the person making the notification;
- The technician’s name and registration number;
- Date of action; and
- Reason for action.

Notification of Technician Action notices may be filed electronically on the Board’s website.

M.5 DISCIPLINED/DISQUALIFIED TECHNICIANS

The Board is statutorily authorized to take the following licensure/disciplinary action against pharmacy technicians:

<table>
<thead>
<tr>
<th>TYPE OF ACTION</th>
<th>DESCRIPTION</th>
<th>AUTHORIZED TO WORK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment Disqualification</td>
<td>Technicians/Applicants disciplined or denied registration for cause under §</td>
<td>NO</td>
</tr>
</tbody>
</table>
SECTION L: PHARMACY TECHNICIANS

### 338.055, RSMo

<table>
<thead>
<tr>
<th>Conditional Registration</th>
<th>Technicians/Technician applicants disciplined under § 338.055, RSMo but allowed to continue working</th>
<th>Yes, subject to restrictions printed on the back of the printed registration.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HB 600 (Tax Suspension)</td>
<td>Technicians suspended by the Missouri Department of Revenue by operation of law for failure to file a tax return or delinquent state taxes.</td>
<td>NO</td>
</tr>
</tbody>
</table>

The Employment Disqualification List, Conditional Registration List and HB 600(Tax) List are available on the Board’s website. These lists are updated frequently. Register for the Board’s e-alerts to receive free electronic updates when individuals are added to the lists.

Licensees are responsible for ensuring technicians are appropriately authorized to work. The Board recommends designating a specific person and setting regular intervals for checking the Board’s listings.

In addition to Board actions, the federal Department of Health and Human Service, Office of the Inspector General Exclusion List (OIG List) includes entities/persons excluded from participating in Medicare, Medicaid and other federal health care programs. Employers participating in qualified federal programs are generally prohibited from employing individuals on the OIG list. For additional information, visit OIG’s website at https://oig.hhs.gov/exclusions/index.asp. Note: OIG exclusions/waivers also apply to pharmacists and interns.

#### REQUIRED FEDERAL WAIVERS

- **WAIVERS**: Both state and federal law prohibit an employer from hiring individuals with certain controlled substance related convictions without an employment waiver. Specifically, a DEA waiver is required for felony controlled substance related convictions. A Missouri BNDD waiver is required for both misdemeanor and felony controlled substance related convictions. Waivers may be required even if the Board has issued a license/registration.

Licensees should conduct thorough background checks to ensure compliance. The Board is legally prohibited from sharing confidential criminal history information. Questions about controlled substance waivers should be addressed to BNDD or the DEA. Note: State/federal waiver requirements also apply to pharmacists and interns.

#### M.6 TECHNICIAN COMPLIANCE RESOURCES

The Board has published a Pharmacy Technician Guide that includes specific compliance information for Missouri technicians. The Board has also published an online Technician Quiz that can be used to test knowledge of Missouri’s technician requirements. The free online quiz can be taken anonymously and can help assess a technician’s understanding of Missouri law.
N.1 LICENSE REQUIREMENTS

A Missouri Class C Long-Term Care pharmacy permit is required if a pharmacy provides prescription services to a long-term care (“LTC”) facility or dispenses legend drugs/devices to patients residing in a LTC facility. [20 CSR 2220-2.140]. A Class C permit is required regardless of the number of patients served (e.g., one patient or the entire long-term care facility). As used in the Board’s rules, a “long-term care facility” is defined as a “nursing home, retirement care, mental care or other facility or institution that provides extended health care to resident patients.” [20 CSR 2220-2.020(9)(C)].

Pursuant to 20 CSR 2220-2.140(2), Class C pharmacies must have a policy and procedure manual that includes:

- Methods for timely dispensing medication;
- Procedures for notifying the facility when a medication is not readily available;
- Labeling requirements and policies;
- Policies/procedures for appropriate medication destruction and/or returning unused medication, as authorized by state and federal law; and
- Policies/procedures for securing, delivering, storing and handling emergency kits.

N.2 AUTHORIZED DISPENSING

Licensees may dispense legend drugs to a LTC resident upon receipt of a prescription or a “prescription drug order.” For purposes of LTC dispensing, a “prescription drug order” is defined as “an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient’s medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device.” [20 CSR 2220-2.140(5)].

Generic substitution is allowed if authorized by the prescriber. [20 CSR 2220-2.140(5)(B)]. Clear documentation of substitution authorization must be maintained, as required by 20 CSR 2220-2.018(1)(H) and 20 CSR 2220-2.080(2)(M).

Pharmacies may maintain a separate file for LTC prescription drug orders, provided that a separate numbering system is used for prescription drug orders. [20 CSR 2220-2.140(5)(C)]. Pharmacies using interim dispensing systems must have records that clearly record these dispensings as any other new or refill dispensing. A pharmacy using an electronic record keeping system must document interim dispensing in the electronic system and may not use a manual record system to record them.

✔ Under 20 CSR 2220-2.140(5)(D), refills associated with a nursing home order are not valid for transfer or use outside of the facility.

N.3 PREPARATION/PACKAGING

Personnel packaging drugs must wear gloves when handling individual tablets and capsules. Drug containers must meet minimum USP requirements, including, but not limited to, single unit, unit dose and unit-of-use containers. [20 CSR 2220-2.140(2)(C)]. If applicable, light sensitive packaging must be used. Internal liners must always be replaced before refilling the container. If drugs are dispensed in a container other than the manufacturer’s original container, the container must bear the manufacturer’s expiration date or a twelve (12) month expiration date, whichever is less. [20 CSR 2220-2.140(3)].
The Board is aware of packaging used by long-term care pharmacies that involve plastic liners within a hard plastic container. These liners must be changed on each initial and refill dispensing.

N.4 LABELING

Containers dispensed to LTC facilities must comply with all state and federal labeling requirements. [20 CSR 2220-2.140(5)(D)]. However, Missouri law authorizes the following exceptions for unit-dose containers:

- The drug name/strength, control number, expiration date and manufacturer’s name may be included on the package, and;
- The patient’s name and directions do not have to appear on the container label if the LTC facility has a mechanism that will identify the medication each patient is to receive, the personnel administering the medication and the directions for administration. [20 CSR 2220-2.140(2)(B)].

A bubble card is not considered a unit-dose container and must bear a full prescription label. All drugs dispensed to a LTC facility must have an expiration date on the container.

In the event of a change in directions, a pharmacist may change the container label, however, the pharmacist must personally affix the revised label. Revised prescription labels may not be sent to the LTC facility for their staff to apply. [20 CSR 2220-2.140(2)(B)].

N.5 RETURN, RE-USE & DISPOSAL

Licensees may receive non-controlled drugs returned from a long-term care facility, hospital or a hospice facility regulated by the Missouri Department of Health and Senior Services under 19 CSR 30-35.020, if:

1) The medication was originally dispensed by the pharmacist or pharmacy to the institution/facility;
2) The pharmacist has assurance from a person at the institution/facility responsible for the medication that the drugs were stored in accordance with the manufacturer’s recommendations and USP standards; and
3) There is an established mechanism to trace the expiration date and the manufacturer’s lot number for the returned medication.

Returned drugs from a long-term care facility, hospital or hospice facility may be reused if:

1) The drug products are returned sealed in the original manufacturer’s tamper-evident packaging; or
2) The drug products were repackaged by a licensed pharmacy or an FDA-registered repackager and are returned sealed in the repackager’s tamper-evident packaging, or;
3) The drug products are returned in unit-of-use packaging and the unused portions can be separated and reused without any further repackaging.

Returned medication from a long-term care/hospice facility or a hospital must be re-labeled to provide accurate patient and prescription information. The original lot numbers, expiration date(s) or beyond-use-date(s) may not be altered.

Information on the drug repository under the jurisdiction of the Missouri Department of Health and Senior Services is available at: http://health.mo.gov/safety/drugrepository/index.php.

Controlled substances may not be returned from a LTC facility.
BOARD OF PHARMACY

- Website
- Publications/Resources Page

Publications
- Certification of Medication Therapeutic Plan Authority Q&A
- Drug Distributor Compliance Guide
- Immunization/Administration Checklist
- Immunization FAQ
- Internet Practice
- Medication Therapy Services Compliance Guide
- Missouri Law Book
- Missouri Pharmacy Practice Guide
- Pharmacist-In-Charge FAQ
- Pharmacy Compliance Top 10
- Pharmacy Inspection Guide

Videos/Webinars
- Available on-demand

MISSOURI BUREAU OF NARCOTICS AND DANGEROUS DRUGS (BNDD)

- BNDD Website
- BNDD Newsletter/Publications
- Controlled Substance Guidelines for Pharmacies
- Mid-Level Practitioner & Controlled Substance Guidelines
- Missouri Changes to Prescriptions Guidelines

DRUG ENFORCEMENT ADMINISTRATION (DEA)

- DEA Website
- Controlled Substances Act
- DEA Rules
- DEA Pharmacist Manual
- DEA Statement on Agents of Prescribers
#A9. **Red Tape Reduction Report/Rule Amendments**

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- 7.025
- 7.027
- 7.030
- 7.040
- 7.050
- 7.070
- 7.080
20 CSR 2220-1.010 General Organization

PURPOSE: The purpose of this regulation is to comply with section 536.023(3), RSMo (1986) which requires each agency to adopt as a regulation, a description of its operation and the methods and procedures where the public may obtain information or make submissions or requests.

(1) The State Board of Pharmacy is a unit of the Division of Professional Registration of the Department of Economic Development Insurance, Financial Institutions and Professional Registration.

(2) The board was created by House Bill No. 87 of the General Assembly of 1909.

(3) The State Board of Pharmacy shall consist of seven (7) persons not connected with any school of pharmacy. Annually the board shall organize by the election of a president and vice president each of whom serves for one (1) year. Six (6) members shall be licensed as pharmacists and actively engaged in the practice of pharmacy within this state and at least one (1) of these shall be a person who provides, on a full-time basis, pharmaceutical services to a hospital, skilled nursing facility or an intermediate care facility. The other member shall be a voting public member. All members shall be appointed by the governor, with the approval of the senate and shall hold their offices for five (5) years from the date of their appointments and until their successors shall have been appointed and qualified.

(4) The board is directed by sections 338.140, 338.280 and 338.350, RSMo to adopt rules for the application and enforcement of Chapter 338, RSMo which also requires compliance of Chapter 195, RSMo.

(5) The board has superintending control over the practice of pharmacy and drug distributors and its primary duties consist of—

(A) Examining and licensing of applicants;
(B) Assisting in the accrediting of pharmacy colleges and approval of their programs;
(C) Renewing annually the license of qualified pharmacists, pharmacies, intern pharmacists and drug distributors;
(D) Suspending, revoking, placing on probation or censure of licenses of any pharmacist, pharmacy, intern pharmacist or drug distributors found guilty of violating the provisions set forth in Chapter 338, RSMo;
(E) Inspecting pharmacies and drug distributors;
(F) Inspecting and certification of pharmacies as intern-training pharmacies;
(G) Interacting and participating with various state and national organizations in order to facilitate the exchange of information, policies and procedures and techniques that can assist the board in fulfilling its mission; and
(H) Interacting with other state and federal agencies as concerns the enforcement of state and federal drug laws.

(6) “Open premises” as used in Chapter 338, RSMo means all premises accessible to employees in the regular course of any business which engages in practices regulated by this chapter, including, but not limited to, locked or otherwise secured storage areas that are used for the purpose of storing drugs, poisons, chemicals, or equipment used in any practice regulated by this chapter, and/or storage areas that are used for the purpose of storing records related to any practice regulated by this chapter.

(7) The public may obtain information from the board, or make submissions or requests to the board, by writing the executive director of the board. The information request shall be reviewed for appropriate action.

[50% Reduction]

**20 CSR 2220-1.020 Board Compensation**

**PURPOSE:** This rule fixes the compensation for the members of the State Board of Pharmacy in compliance with the mandates of section 338.130, RSMo (1986).

1. *Except as otherwise authorized by law,* each member of the State Board of Pharmacy shall receive as compensation the sum of fifty dollars ($50) for each day that member devotes to the affairs of the board.

2. In addition to the compensation fixed in this rule, each member is entitled to reimbursement of his/her expenses necessarily incurred in the discharge of his/her official duties.

3. No request for the compensation provided in this rule shall will be processed for payment unless sufficient funds are available for that purpose within the appropriation for this board.


20 CSR 2220-2.015 Termination of Business as a Pharmacy

PURPOSE: This rule establishes guidelines for the termination of business as a pharmacy.

(1) A licensed pharmacy who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within fifteen (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the licensee and shall include the following information:

(A) The name, address, license (permit) number and effective date of closing;
(B) The name, address, and license (permit) number of the entity to which any of the stock/inventory will be transferred;
(C) The name and address of the location to which records, required to be maintained by law, have been transferred.

1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board.
2. Any records that are transferred to a licensed (permitted) pharmacy or licensed drug distributor must be maintained in accordance with record requirements as set forth in section 338.100, RSMo.

(2) The licensee (permit holder) terminating business may transfer all drugs and records in accordance with the following:

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the pharmacy terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee or permit holder involved in the transfer.

(B) A pharmacy terminating business shall not transfer No misbranded, outdated or adulterated drugs may be transferred, except for purposes of proper disposal; and

(C) Upon the actual termination of business, the license (permit) of the pharmacy shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) A one (1)-time transfer of drugs and devices due to a termination of business that is in compliance with this rule will not require a pharmacy to seek licensure as a drug distributor under sections 338.330 and 338.333, RSMo.
(4) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a pharmacy.

(5) The termination date is the date on which the permit holder ceases to practice pharmacy as defined in sections 338.010 and 338.210, RSMo, at the permitted location.


20 CSR 2220-2.016 Pharmacy Operating Procedures During Declared Disasters

PURPOSE: This rule is to establishes guidelines for the operation and temporary relocation of a pharmacy during a declared disaster.

(1) Declared disaster areas are defined as specified geographical counties within the state that have been designated by the governor or federal authorities as counties that have been adversely affected by a natural or man-made disaster and requires extraordinary measures to provide adequate, safe and effective health care for the affected population.

(2) In cases where a disaster as defined in section (1) has been declared, any pharmacy located within the disaster area may arrange to move to a temporary location to better serve the public or provide pharmacy services from a mobile unit that is under the control and management of the pharmacist-in-charge.

(A) The following constitutes requirements for maintaining temporary or mobile facilities. Temporary or mobile facilities must comply with the following:

1. Temporary or mobile pharmacy facilities shall may only be located within the disaster area or adjacent county;

2. Temporary facilities may be maintained by a pharmacy operation for a period of up to six (6) months without applying for a change of location. Any pharmacy wishing to maintain a temporary site for more than six (6) months or desires to remain permanently at the temporary site, must apply for a change of location as outlined in 4 CSR 220-2.020(4);

3. Mobile pharmacy operations must cease services once the immediate disaster is over;

4. Temporary or mobile pharmacy facilities must inform the board of their location and provide an estimate of the time period for which the temporary or mobile pharmacy operation will be needed; and

5. The executive director shall have the authority to approve or disapprove temporary or mobile pharmacy facilities and shall make arrangements for appropriate monitoring and inspection of the pharmacy on a case by case basis.

A. Approval of this type of operation will be based on the need, type and scope of disaster, as well as the ability of the pharmacy to comply with state and federal drug laws in addition to section 338.240, RSMo.

B. Temporary or mobile pharmacy facilities shall cease may not continue operations under the provisions of this rule if any previous approval is withdrawn.
C. Any decision made concerning the approval of a temporary or mobile pharmacy shall *not* interfere with any rights or privileges of a pharmacy permit holder at the original location of operation or prevent a permit holder from applying for a change of location as outlined in 4 CSR 220-2.020(4) the Board’s rules.


20 CSR 2220-2.050 Public Complaint Handling and Disposition Procedure

PURPOSE: This rule establishes a procedure for the receipt, handling and disposition of public complaints by the board, pursuant to the mandate of section 620.010.16(6), RSMo.

(1) The State Board of Pharmacy shall receive and process each complaint made against any licensee or registrant or other person or entity, which complaint alleges certain acts or practices which may constitute one (1) or more violations of the provisions of Chapter 338, RSMo. Any member of the public, the profession or any federal, state or local official may make and file a complaint with the board. Complaints shall be received from sources outside Missouri and will be processed in the same manner as those originating within Missouri. No member of the State Board of Pharmacy shall file a complaint with this board while s/he holds that office, unless that member excuses him/herself from further board deliberations or activity concerning the matters alleged within that complaint. Any staff member or employee of the board may file a complaint pursuant to this rule in the same manner as any member of the public.

(2) Complaints should be mailed or delivered to the following address: State Board of Pharmacy, 3605 Missouri Blvd., PO Box 625, Jefferson City, MO 65102. However, actual receipt of the complaint by the board at its administrative offices in any manner shall be sufficient. Complaints may be based upon personal knowledge or upon information and belief, reciting information received from other sources.

(3) Except as otherwise authorized by the Board or the Executive Director, all complaints shall be made in writing and shall fully identify their maker by name and address. Complaints may be made on forms provided by the board, which are available upon request. Complaints need not be made by affidavit, but oral or telephone communications will not be considered or processed as complaints unless otherwise authorized by the Board or the Executive Director. Any person attempting to make an oral or telephone complaint against an individual will be provided with a complaint form and requested to complete it and return it to the board. Any staff member or employee of the board may make and file a complaint based upon information and belief, in reliance upon oral, telephone or written but unsigned communications received by the board, unless those communications are believed by that staff member or employee to be false.
Each complaint received under this rule shall be recorded by the board. Complaints shall be logged in consecutive order as received. The record shall contain each complainant’s name and address; the name and address of the subject(s) of the complaint; the date each complaint is received by the board; a brief statement of the acts complained of, and the ultimate disposition of the complaint. This record shall be a closed record of the board.

The complainant shall be informed in writing as to whether the complaint has been dismissed by the board or is being referred to legal counsel for legal action. The complainant may be notified of the ultimate disposition of the complaint, excluding judicial appeals and may be provided with a copy of the decisions (if any) of the Administrative Hearing Commission and the board. The provisions of this section shall not apply to complaints filed by staff members or employees of the board, based upon information and belief, acting in reliance on third-party information received by the board.

Both the complaint and any information obtained as a result of the complaint investigation shall be considered a closed record of the board and shall not be available for inspection by the public.

This rule shall not be deemed to limit the board’s authority to file a complaint with the Administrative Hearing Commission or with a court, charging a licensee, permittee or other person or entity with any actionable conduct or violation, whether or not this complaint exceeds the scope of the acts charged in a preliminary public complaint filed with the board and whether or not any public complaint has been filed with the board.

The board interprets this rule, which is required by law, to exist for the benefit of those members of the public who submit complaints to the board. This rule is not deemed to protect, or to inure to the benefit of those licensees, permit holders, registrants or other persons or entities against whom the board has instituted or may institute administrative or judicial proceedings concerning possible violations of provisions of Chapter 338, RSMo.

To facilitate the investigation, evaluation and disposition of complaints, which involve violations of federal and state law governing controlled substances, the Board of Pharmacy may designate Bureau of Narcotics and Dangerous Drugs personnel and other state personnel as pharmacy inspectors. These inspectors shall be authorized pursuant to section 338.150, RSMo to enter and inspect various premises.

Persons designated by the Board of Pharmacy as pharmacy inspectors and other Board of Pharmacy personnel may attend board meetings in order to assist the board in its deliberations.


SHALL= 4/0
MUST= 0
[100% Reduction]

20 CSR 2220-2.060 Gold Certificates

 PURPOSE: This rule sets requirements concerning the issuance of honorary gold certificates to pharmacists licensed in Missouri for fifty years.

(1) The Missouri Board of Pharmacy shall may issue gold certificates to all pharmacist licensees who have been regularly licensed as pharmacists in Missouri for fifty (50) years without charge to the recipient. These gold certificates shall be distinctive in coloration and text from other documentary licenses issued by the board and shall be designed to appropriately recognize each recipient pharmacist for his/her half century of professional practice. Gold certificates are honorific in nature and confer no right to practice pharmacy upon the recipient.

(2) The awarding of gold certificates shall be made by the Missouri Board of Pharmacy routinely and without charge to the recipient.


20 CSR 2220-2.080 Electronic Prescription Records

PURPOSE: This rule establishes requirements for utilizing an electronic data-processing system in a pharmacy.

(1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall may be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.

(2) EDP systems shall comply with the requirements of section 338.100, RSMo, and shall be capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:
   (A) A unique, sequential prescription label number;
   (B) If applicable, a unique readily retrievable identifier;
   (C) Date the prescription was prescribed;
   (D) The date the prescription was initially filled and the date of each refill;
   (E) Patient’s full name, or if an animal, the species and owner’s name;
   (F) Patient’s address or animal owner’s address when a prescription prescribes a controlled substance;
   (G) Prescriber’s full name;
   (H) Prescriber’s address and Drug Enforcement Administration (DEA) number when a prescription specifies a controlled substance;
   (I) Name, strength and dosage of drug, device or poison dispensed and any directions for use;
   (J) Quantity originally dispensed;
   (K) Quantity dispensed on each refill;
   (L) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
(M) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;

(N) The number of authorized refills and quantity remaining;

(O) Whether generic substitution has been authorized by the prescriber;

(P) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and

(Q) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail—This shall include, including, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(3) The information specified in section (2) shall be required and recorded in the EDP system prior to dispensing by a pharmacist or pharmacy.

(4) Except as otherwise provided by 20 CSR 2220-2.083, prescription hard copies must be maintained and filed by either the sequential prescription label number or by a unique readily retrievable identifier. For verbal, telephone, or electronic data transmission prescriptions, a hard copy representation of the prescription shall be made and filed which contains all of the information in section (2). Prescription hard copies must be retrievable at the time of inspection, except as otherwise provided by 20 CSR 2220-2.010(1)(J). For purposes of this subsection an electronic data transmission prescription shall be defined as provided in 20 CSR 2220-2.085.

(5) If additional refills are authorized and added to a prescription, a notation indicating the method and source of the authorization must be a part of the EDP record or hard copy, in that case the expiration date of the original prescription shall remain the same.

(6) Any hospital pharmacy using an EDP system licensed by the board, as described in section (1), for outpatient prescriptions, employee prescriptions, and take-home prescriptions shall conform to all sections of this rule.

(7) Any EDP system must be capable of producing the record required by this rule and said records shall be readily retrievable online. Readily retrievable is defined as providing EDP records immediately or within two (2) hours of a request by an inspector or by making a computer terminal available to the inspector for immediate use.

(8) An auxiliary record-keeping system shall be established for the documentation of refills if the EDP system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription or prescriber. When this EDP system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the EDP system within seven (7) working days. However, nothing in this section shall preclude the pharmacist from using his/her professional judgment for the benefit of a patient’s health and safety.

(9) If a prescription is transferred from a pharmacy using an EDP system, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the original pharmacy, it shall be treated as a new record, showing the original date written and expiration date.
Prior to or simultaneously with the purging of any EDP system, the permit holder shall make certain that a record of all prescription activity being erased exists in readable form, either on paper, microfiche, or electronic media storage. A pharmacy that desires to discard hard copy prescriptions that are more than three (3) years old must maintain all prescription information on microfiche or electronic media. Any process utilizing microfiche must ensure that all data is available and in readable form. Any pharmacy opting for the utilization of microfiche records must also maintain a microfiche reader so that records may be reviewed on-site by pharmacy personnel or board inspectors. Electronic media storage is defined as any medium such as a computer, floppy disk or diskette, compact disk (CD), or other electronic device that can reproduce all prescription information as required by section 338.100, RSMo, and this rule and is retrievable within three (3) working days.

If coded information exists in the electronic EDP, the board inspector may request the definitions of the codes from the pharmacist on duty for immediate review.

The EDP system shall be able to provide a listing of drug utilization by date for any drug for a minimum of the preceding twenty-four- (24-) month period. Drug utilization information shall be available by date(s), that includes the specific drug product, patient name, or practitioner. If requested to do so, the pharmacy shall have three (3) working days to provide the report.

The provisions of this rule shall not conflict with do not preempt any federal laws or regulations. If any part of this rule is declared invalid by a court of law, that declaration shall not affect the other parts of the rule.

Licensees shall also comply with all state and federal controlled substance record keeping requirements, including, any required daily log books or printouts.


20 CSR 2220-2.110 PRN Refills

PURPOSE: This rule clarifies the board’s requirements for refills as needed so that the practicing pharmacists in Missouri will have adequate guidelines in this area.

(1) A pharmacist shall not fill or refill any prescription which was written more than one (1) year before being presented to the pharmacist, unless the pharmacist consults with the prescriber and confirms—
   (A) That the person for whom the drugs or medicines were prescribed is still under the prescriber’s care or treatment;
   (B) That the prescriber desires for the person to continue receiving the drugs or medicines; or
   (C) If the prescriber answers negatively in either case listed in subsection (1)(A) or (B), the pharmacist shall not fill or refill the prescription may not be filled or refilled, even if the prescription authorizes refills as needed (PRN).

(2) If a pharmacist knows or has reason to believe that a person for whom a prescription has been written is not under the prescribers care or treatment at the time the prescription is presented for filling or refilling, the pharmacist shall consult with their prescriber and ascertain that the prescriber intends for the person to receive the drugs or medicines. The pharmacist shall do this Prescriber consultation is required no matter when the prescription originally was written and even if the prescription authorizes refills PRN.

(3) After the pharmacist has confirmed the information required in sections (1) and (2) of this rule, s/he shall record it in his/her records in a uniform fashion so as to make it readily available for verification by the board or its authorized agents.


PURPOSE: This rule defines record keeping required for the transfer of prescription information for the purpose of refill.

(1) Prescription information shall be transferred for the purposes of refill between licensed pharmacies, provided the prescription information to be transferred meets all of the following criteria:
   A. The prescription information indicates authorization by the prescriber for refilling;
   B. The drug on the prescription information is not a Schedule II controlled substance;
   C. The number of lawfully allowable refills has not been exceeded or the maximum allowable time limit has not been exceeded;
   D. If the transfer involves a controlled substance, all information must be transferred directly between two (2) licensed pharmacists; and
   E. The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one (1)-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber’s authorization.

(2) When a prescription on record is transferred, the following record keeping is required:
   A. The prescription record at the transferring pharmacy shall show all of the following:
      1. The word void must appear on the face of the invalidated prescription or be immediately voided within the electronic system when the prescription is transferred;
      2. The prescription record shall provide the name of the pharmacy to which it was transferred, the date of transfer and the identity of the transferring pharmacist; and
      3. If the transfer involves a controlled substance, the address and Drug Enforcement Administration (DEA) registration number of the pharmacy to which it was transferred and the full name of the pharmacist receiving the prescription information must be recorded;
   B. The prescription record at the receiving pharmacy shall show all of the following, in addition to all other lawfully required information of an original prescription:
      1. The prescription record is a transferred prescription record from another licensed location;
      2. Date of original issuance;
      3. Date of original filling, if different from original issuance date;
      4. Original number of refills authorized on the original prescription and the number of remaining authorized refills;
      5. Date of last refill;
      6. Prescription label number;
7. Identity of licensed pharmacy from which the record was transferred;
8. The identity of the transferring pharmacist provided that pharmacies that share the same database and are under the same ownership may, instead of transferring prescriptions directly between two (2) pharmacists, transfer a prescription electronically by generating a computer-based report at the transferring pharmacy of any prescriptions that have been transferred out. This record shall be readily retrievable to the transferring pharmacy and board representatives and comply with all of the requirements of this rule, except that the requirement to document pharmacist identity shall not be required; pharmacist’s identity does not have to be documented unless otherwise required by federal law;
9. If the transfer involves a controlled substance, the address and DEA registration number from the transferring pharmacy must be recorded; and
10. Any electronic transfer must maintain patient confidentiality in accordance with 20 CSR 2220-2.300; and
(C) A computerized transfer of prescription information between licensed pharmacies for the purpose of refill shall meet all the requirements stated in sections (1) and (2) of this rule.

(3) A pharmacy shall complete the transfer within one (1) business day of receiving the request.

(4) When a transfer of prescription information for the purpose of filling an original prescription occurs, all provisions of this rule must be followed, except for subsection (1)(C) and paragraphs (2)(B).4–.6. This paragraph is in 6.030 but should be in this rule; staff recommends rescinding 6.030.


20 CSR 2220-2.150 Mandatory Reporting Rule

PURPOSE: This rule defines the responsibilities of a director of pharmacy or the pharmacist-in-charge, or both, in a hospital or ambulatory surgical center in reporting disciplinary actions against pharmacist employees to the chief executive officer of the employing institution.

(1) The board of pharmacy shall receive and process any report from a hospital or ambulatory surgical center concerning any disciplining action against a licensed pharmacist or the voluntary resignation of any licensed pharmacist against whom any complaints or reports have been made which might have led to final disciplinary action.

(2) Reports to the board from a hospital or ambulatory surgical center concerning any disciplinary action against a licensed pharmacist or the voluntary resignation of any licensed pharmacist against whom any complaints or reports have been made which might have led to final disciplinary action shall comply with the minimum requirements as set forth in section 383.133, RSMo and this rule. This information shall include, but not be limited to and include at minimum:

(A) The name, address and telephone number of the person making the report;
(B) The name, address and telephone number of the person who is the subject of the report;
(C) A brief description of the facts which gave rise to the issuance of the report, including the dates of occurrence deemed to necessitate the filing of the report;
(D) If court action is involved and known to the reporting agent, the identity of the court, including the date of filing and the docket number of the action;
(E) A statement as to what final action was taken by the institution; and
(F) That the report is being submitted in order to comply with the reporting provisions of Chapter 383, RSMo.

(3) The director of pharmacy or pharmacist-in-charge shall report any actions as described in section (1) to the chief executive officer (CEO) or his/her designee. (2) Any activity that is construed to be a cause for disciplinary action according to section 338.055, RSMo or results in potential or actual harm to the public shall be deemed reportable to the board. Nothing in this rule shall be construed as limiting or prohibiting This rule does not limit or prohibit any pharmacist from reporting a violation of the Pharmacy Practice Act directly to the Missouri Board of Pharmacy.
(4) In response to an inquiry from a hospital or ambulatory surgical center regarding reports received by the board on a specific pharmacist, the board shall provide the following information:

(A) Whether any reports have been received;
(B) The nature of each report; and
(C) The action which the board took on each report or if the board has taken action on the report.

(5) Each report received shall be acknowledged in writing. The acknowledgment shall state that the report is being reviewed by the board or is being investigated and shall be referred to the board or an appropriate board subcommittee for consideration. The institution subsequently shall be informed in writing as to whether the report has been dismissed by the board or is being referred to legal counsel for filing with the Administrative Hearing Commission or for other legal action. The institution may be notified of the ultimate disposition of the report excluding judicial appeals and may be provided with a copy of the decisions (if any) of the Administrative Hearing Commission and the board.

(6) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction.


20 CSR 2220-2.170 Procedure for Impaired Pharmacist

PURPOSE: This rule establishes an efficient and timely process for the disposition of information and tentative board action concerning impaired pharmacists to the attorney general’s office for purposes of preparing a complaint and streamlines the procedure utilized in interviewing pharmacists who are chemically impaired.

(1) The executive director shall receive information concerning the impairment of licensees and coordinate any investigations that seek to substantiate information concerning a possible impairment.

(2) Investigations by board inspectors or division investigators concerning chemically impaired licensees will be collected and reviewed by the executive director. Cases will be divided into two categories.

(A) Category A. Chemically impaired licensees where additional information is evident that known distribution of controlled substances or legend drugs to other individuals has taken place.

(B) Category B. Chemical impairment of a licensee where controlled substances, legend drugs or alcohol have been acquired for personal use only.

(3) Cases which fall into Category A will be referred to the board for appropriate action.

(4) Cases which fall within Category B will be subject to administrative review as a preliminary action to facilitate any corrective actions deemed necessary by the board.

(5) The following shall constitute office procedures involving Category B cases:

(A) The president of the Board or other Board member designated by the president may authorize the Executive Director or other Board designee to hold an administrative review fact-finding meeting with a licensee or other applicant suspected of possible impairment, substance abuse/misuse, chemical dependency or other incapacity:

   (i) Normal procedures for completing field investigations and assimilating other pertinent information will be followed;

   (ii) If the director believes that a case falls into Category B of this policy, s/he shall consult with the president of the board concerning the appropriateness of an administrative review;
(C) If approval by the president is given, the director shall take actions necessary to set up a meeting with the licensee who is the subject of the investigation. In addition, other individuals such as legal counsel for the board may be asked to attend, along with any staff member, as necessary.

(D) A statement concerning due process procedures and the rights of the licensee will be read at the beginning of the review meeting. A complete record of the administrative review meeting shall be maintained by the board office. Notice that the president of the board has been notified and that s/he has given approval for an administrative fact-finding meeting shall be entered into the record;

(E) A format during the fact-finding meeting will be followed that allows the licensee to provide a statement of his/her own as well as a question/answer period allowed to discuss the aspects of the case centering on the chemical impairment issues or on any related concerns about the individual’s ability to practice pharmacy;

(F) After the fact-finding meeting is concluded, a summary will be provided to each member of the board within the appropriate agenda, along with recommendations from the director as to any action to be taken. In addition, the president will be contacted and provided any follow-up information that could warrant changes in administrative procedures. The president, by executive order, may initiate an affidavit to the board attorney of an intent to file a complaint with the Administrative Hearing Commission. Once an order is executed, the information on the case shall be forwarded to the attorney for necessary legal preparation; and

(G) The entire board shall consider the case in closed session as to whether or not to file a complaint against the licensee and consider the recommendations made as to terms. Once the board authorizes a complaint, the attorney for the board shall assure that the appropriate filings take place.

(6)(2) When an impaired pharmacist—licensee or registrant—is disciplined by the board and a term of the discipline is that s/he participate in a chemical dependence treatment program, the impaired pharmacist shall select a program which meets the following guidelines unless otherwise approved or requested by the Board or the Board’s authorized designee:

(A) Persons who are involved in the treatment or counseling of a Missouri board-licensed pharmacist must submit written documentation of their credentials and qualifications to provide treatment or counseling;

(B) A written agreement or contract must be provided and executed between the counselor(s) and the licensee, outlining the responsibilities of each party for a successful treatment and monitoring program. The agreement must include a provision for sharing information concerning all aspects of therapy between the treatment facility or counselors, or both, and the Missouri Board of Pharmacy;

(C) An initial written evaluation report must be completed and provided to the board outlining the licensee’s present state of impairment, the recommended course(s) of treatment, the beginning date of treatment and an assessment of future prospects for recovery;

(D) A copy of the proposed treatment plan must be provided to the board and must include a provision outlining the method of referral to an appropriate after-care program;

(E) The counselor(s) must provide written progress reports to the board as follows:
   1. Inpatient therapy—monthly reports;
   2. Outpatient therapy—quarterly reports; and
   3. After-care programs—semiannual reports;
(F) The treatment program must include randomized and witnessed body fluid testing and analysis, with any drug presence not supported by a valid prescription to be reported to the Missouri Board of Pharmacy; and

(G) The treatment program must include a provision for reporting any violation of the treatment contract or agreement by the licensee to the board; and

(H) All reports outlined in this protocol must be provided in writing to the board for a counselor or treatment facility, or both, to be approved for the treatment of a licensee undergoing disciplinary board action.


20 CSR 2220-2.175 Well-Being Program

PURPOSE: This rule establishes guidelines for the operation of the Well-Being Committee, pursuant to section 338.380, RSMo.

(1) Definitions.
   (A) Board—State Board of Pharmacy.
   (B) Committee administrator—The person who is hired by the contractor or the committee to oversee and manage the Well-Being Program.
   (C) Contractor—An entity with whom the board contracts for the purpose of creating, supporting, and maintaining the Well-Being Program.
   (D) Impairment—An illness, substance abuse, or physical or mental condition suffered by a licensee that is reasonably related to the ability to practice pharmacy.
   (E) Licensee—Pharmacist, intern pharmacist, or technician licensed or registered in the state of Missouri or who has applied for licensure or registration in the state of Missouri.
   (F) Well-Being Committee—The committee established pursuant to section 338.380, RSMo, for the purpose of promoting the early identification, intervention, treatment, and rehabilitation of pharmacists, intern pharmacists, and technicians who may be impaired by reasons of illness, substance abuse, or as a result of any physical or mental condition.
   (G) Well-Being Program—The activities and functions of the Well-Being Committee.

(2) The board may contract with a contractor for purposes of creating, supporting, and maintaining the Well-Being Program. The Well-Being Committee may assist the board in the identification, selection, and evaluation of the contractor, as requested by the board. Operational costs of the Well-Being Program may be paid by the board, subject to available funding. All costs of drug screens and professional and administrative services provided to a licensee shall be paid by the licensee. Except as otherwise funded by the Board, licensees are responsible for all drug screen costs and costs for professional and administrative services provided to the licensee.

(3) Membership and Organization.
   (A) The Well-Being Committee (hereinafter committee) shall be composed of the committee administrator and three (3) appointed members as follows:
      1. One (1) member designated by the Missouri Pharmacy Association;
      2. One (1) member designated by the Missouri Society of Health-System Pharmacists; and
      3. One (1) member designated by the State Board of Pharmacy.
   (B) The appointed committee members shall serve staggered three (3)-year terms and may serve as many terms as their respective organizations deem appropriate. The entity designating a
member to the committee shall designate a person to finish the three (3)-year term of any member of the committee who becomes unable to serve.

(C) The committee shall meet at least two (2) times annually and annually elect a chairperson.

(D) The committee shall meet at least two (2) times annually.

(E) The appointed committee members shall serve without compensation will be provided to appointed committee members other than that allowed by law for service as a board member. Each appointed committee member shall be entitled to reimbursement for travel expenses as deemed appropriate by the board.

(E) The committee administrator shall be a nonvoting member of the committee.

(4) An impaired licensee may enter the Well-Being Program voluntarily or by referral of the board pursuant to a settlement agreement or other disciplinary order. Licensees entering the Well-Being Program voluntarily shall be subject to and comply with all requirements of this rule.

(5) Well-Being Committee Duties.

(A) The committee shall oversee all aspects of the general operation of the contractor including, but not limited to, oversight of the administration, staffing, financial operations, and case management of the Well-Being Program.

(B) The committee shall assist the board in monitoring the impaired licensee’s compliance with the terms of any disciplinary order/agreement. and

(C) The committee shall provide the board access to all information and documents pertaining to impaired licensees referred to the Well-Being Program by the board.

(D) The committee shall enter into written contracts with each impaired licensee. The contract between the committee and the impaired licensee shall be a minimum of five (5) years in duration, or the time designated by the board. At a minimum, the contract between the committee and impaired licensee shall include, but not be limited to, the following requirements:

1. Each impaired licensee shall comply with all terms, conditions, or treatment identified, required, or recommended by the contractor or the board for the treatment, evaluation, monitoring, or assessment of the impaired licensee;

2. Each impaired licensee shall abstain from the possession or consumption of legend medication, except as prescribed by a treating prescriber;

3. Each impaired licensee shall abstain from illegal possession of alcohol, the consumption of alcohol, and the possession or consumption of illegal drugs;

4. Each impaired licensee shall submit to random drug testing unless otherwise specified by the board, committee, or contractor;

5. Each impaired licensee shall report to the committee or the contractor all relapses or other breaches of the contractual terms;

6. Each impaired licensee shall report to or meet with the board, committee, contractor, or the contractor’s appointed designee as may be requested by the board, committee, or contractor;

7. Each impaired licensee shall attend support meetings as requested by the committee, contractor, or treatment providers;

8. Each impaired licensee referred to the Well-Being Program by the board shall authorize the committee to release any and all information regarding the impaired licensee to the board;
Each impaired licensee voluntarily enrolled in the Well-Being Program shall authorize the committee to release any and all information regarding the impaired licensee to the board upon a violation of any state or federal drug law or if the licensee breaches or fails to comply with any terms of a Well-Being contract; and

Each impaired licensee shall be financially responsible for all drug screens and any other professional or administrative service rendered on behalf of the impaired licensee.

The committee shall provide to the board in writing:

1. An annual action plan and budget to be approved by the board. The committee shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board or committee;

2. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program. The identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board for purposes of these reports, except as otherwise provided by this rule. Progress reports shall be provided to the board at board meetings or upon request of the board;

3. Except as otherwise provided by this rule for voluntary participants, any and all information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee who participates in, or is assisted by, the Well-Being Program;

4. Quarterly income and expense reports. These reports must be itemized and account for all income from any and every source and each expense to any and every vendor that relates to the Well-Being Program in any way; and

5. Any other report or information requested by the board, except as otherwise provided by this rule for voluntary participants.

In addition to the other requirements of this rule, the committee shall also report, in writing, to the board:

1. All licensee violations of board disciplinary orders/agreements, board statutes or regulations, or other state or federal drug laws which occur after the date of the disciplinary order/agreement or the date the licensee entered the Well-Being Program, whichever occurs first;

2. Any licensee who fails to enter treatment within forty-eight (48) hours following the provider’s determination that the licensee needs treatment;

3. Any licensee who does not comply with the terms of a Well-Being Program contract or who resumes the practice of pharmacy before the treatment provider has made a clear determination that the licensee is capable of practicing; and

4. Any breach of contract by the Well-Being Committee or the committee administrator.

The identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board, provided that upon receipt of a Notice of Non-Compliance from the contractor, the committee shall promptly file a complaint with the board against the licensee identified in the notice. The complaint required by this subsection shall include the impaired licensee’s name, license number, and the factual basis for the alleged contractual breach/non-compliance. Upon the filing of a complaint, the committee shall require the committee administrator to supply to the board any information or documentation with regard to the licensee’s identification, intervention, treatment, compliance, and rehabilitation, as requested by the board or their designated representative.

The committee shall require the costs of drug screens and professional and administrative services to be paid by the impaired licensee.

(6) Committee Administrator Duties.
(A) The committee administrator shall oversee and manage the daily operations of the committee and assist with the administrative duties of the committee.

(B) The committee administrator shall possess a combination of education and experience in the area of addiction counseling and be currently licensed in Missouri as a psychologist, psychiatrist, professional counselor, or clinical social worker. Upon request of the committee, the board may waive the licensure requirements of this subsection for qualified applicants that otherwise possess an equivalent combination of education and experience, as required by this rule.

(C) The committee administrator shall also be familiar with licensees suffering from impairment issues which include, but shall not be limited to, the following:
   1. Dependency;
   2. Alcohol addiction;
   3. Drug addiction;
   4. Other addictive diseases;
   5. Physical issues; and
   6. Mental health issues.

(D) Upon referral, the duties of the committee administrator shall also include, but are not limited to, assisting the committee with the following:
   1. Organizing and carrying out interventions;
   2. Referring licensees for appropriate assessment or evaluation and seeing that treatment recommendations based on the assessment are followed;
   3. Monitoring treatment progress and re-entry contractual compliance;
   4. Managing/monitoring random drug screens;
   5. Assisting licensees to re-enter practice from treatment;
   6. Assisting with aftercare issues;
   7. Any and all reporting to appropriate agencies, as requested by the board or the committee;
   8. Program development;
   9. Outreach education, as requested by the committee; and
   10. Other necessary services as determined by the committee.

(E) Upon request by the committee, the committee administrator shall supply to the committee in writing:
   1. Any information or documentation regarding the operation of the Well-Being Program;
   2. All information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee that is participating in or being assisted by the Well-Being Program or who has participated in or been assisted by the Well-Being Program;
   3. Progress reports to the committee with regard to each licensee participating in the Well-Being Program; and
   4. Any reports provided to the board.

(F) Upon request, the committee administrator shall supply to the board in writing:
   1. Any information requested by the board regarding the Well-Being Program or any licensee participating in or being assisted by the Well-Being Program, except as otherwise provided herein for voluntary participants; and
   2. Any information or documentation with regard to the identification, intervention, treatment, rehabilitation, and compliance of any voluntary participant who breaches or fails to comply with the terms of any Well-Being Program contract or violates any state or federal law.

(7) Contractor Duties.
(A) Upon referral, the contractor shall be responsible for requiring evaluators to provide written reports which address whether a participant of the Well-Being Program suffers from an impairment, identifies the impairment, provides recommendations for treatment of the impairment, and whether the participant’s practice of pharmacy should be restricted due to the impairment; and

(B) The contractor shall provide services when appropriate to impaired licensees which include, but are not limited to, the following:

1. Monitoring compliance of the contract between the committee and the impaired licensee;
2. Assisting the impaired licensee in obtaining evaluation and treatment;
3. Ensuring that treatment recommendations based on the assessment of the licensee are followed;
4. Monitoring treatment progress and re-entry contractual compliance;
5. Managing/monitoring random drug screens;
6. Assisting licensees to re-enter practice from treatment;
7. Assisting with aftercare issues;
8. Any and all reporting to appropriate agencies, as requested by the board or the committee;
9. Program development;
10. Outreach education, as requested by the committee;
11. Managing, ensuring, and monitoring random and scheduled drug screens; and
12. Other necessary services as determined by the committee.

(C) The contractor shall assist the board in monitoring the impaired licensee’s compliance with the terms of any disciplinary order/agreement.

(D) The contractor shall obtain a written release from all licensees referred to the Well-Being Program that authorizes the contractor to release to the board, the committee, or the committee administrator all information and documents pertaining to a licensee referred by the board.

(E) Voluntary Participants.

1. Except as otherwise provided in this subsection, the identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board.
2. The contractor shall file with the committee a Notice of Non-Compliance against any voluntary participant who breaches or fails to comply with the terms of any Well-Being Program contract or who violates any state or federal drug law. If a complaint is filed by the committee against the licensee, the contractor shall require the committee administrator to supply to the board any information or documentation with regard to the licensee’s identification, intervention, treatment, compliance, and rehabilitation, as requested by the board.
3. The contractor shall obtain a written release from all licensees who voluntarily enter the Well-Being Program that authorizes the contractor to release any and all information or documents pertaining to the licensee to the board or the committee in the event the licensee breaches or fails to comply with the terms of any Well-Being Program contract or violates any state or federal drug law.

(F) General Reporting.

1. The contractor shall provide to the committee in writing:
   A. An annual action plan and budget to be approved by the board. The contractor shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board or committee;
   B. Quarterly income and expense reports for the Well-Being Program and any other financial report requested by the board or the committee;
C. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program;
D. Any reports provided to the board;
E. Any and all information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee who participates in, or is assisted by, the Well-Being Program;
F. Any other report or information requested by the committee; and
G. The information and documentation required by this subsection shall only be released to the board pursuant to Chapter 338, RSMo, and the rules promulgated thereto.

2. The contractor shall provide to the board in writing:
   A. An annual action plan and budget as directed by the board. The contractor shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board or committee;
   B. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program, provided the identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board for purposes of these reports, except as otherwise provided by this rule; and
   C. Any other report or information requested by the board, except as otherwise provided by this rule for voluntary participants.

(G) Violation Reporting. In addition to the other requirements of this rule, the contractor shall report, in writing, to the committee:
1. All licensee violations of a board disciplinary order/agreement, any provision of Chapter 338, RSMo, or the board regulations, or any state or federal drug law, which occurs after the date of the disciplinary order/agreement or the date the licensee entered the Well-Being Program, whichever occurs first;
2. Any licensee who fails to enter treatment within forty-eight (48) hours following the provider’s determination that the licensee needs treatment; and
3. Any licensee who does not comply with the terms of a Well-Being Program contract or who resumes the practice of pharmacy before the treatment provider has made a clear determination that the licensee is capable of practicing.

(H) The contractor shall require the costs of drug screens and professional and administrative services to be paid by the impaired licensee.

(8) Confidentiality.

(A) The committee and contractor shall provide the board access to all information pertaining to each impaired licensee referred to the committee by the board.

(B) In regards to participants referred by the board and the voluntary participants who have violated or breached their Well-Being Program contracts, the board and committee may exchange privileged and confidential information, interviews, reports, statements, memoranda, and other documents including information on investigations, findings, conclusions, interventions, treatment, rehabilitation, and other proceedings of the board and committee, and other information closed to the public to promote the identification, interventions, treatment, rehabilitation, and discipline (accountability) of licensees who may be impaired.

(C) All privileged and confidential information and other information not considered to be public records or information pursuant to Chapter 610, RSMo, shall remain privileged and confidential and closed to the public after such information is exchanged.

20 CSR 2220-2.300 Record Confidentiality and Disclosure

PURPOSE: This rule establishes requirements for the confidentiality and disclosure of records related to patient care.

(1) Prescription records, physician orders and other records related to any patient care or medical condition(s) of a patient that are maintained by a pharmacy in accordance with section 338.100, RSMo shall be considered confidential. Adequate security shall be maintained over such records in order to prevent any indiscriminate or unauthorized use of any written, electronic or verbal communications of confidential information.

(2) Confidential records shall not be released to anyone except—
   (A) The patient;
   (B) A health care provider involved in treatment activities of the patient;
   (C) Lawful requests from a court or grand jury;
   (D) A person authorized by a court order;
   (E) Any other person or entity authorized by a patient to receive such information;
   (F) For the transfer of medical or prescription information between pharmacists as provided by law;
   (G) Government agencies acting within the scope of their statutory authority; or
   (H) A person or entity to whom such information may be disclosed under 45 CFR Parts 160, 164 and 165 (the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996) or other applicable state/federal law.

(3) This rule does not change or otherwise alter the authority of the board, its inspectors or other authorized designees to review, inspect, copy or take possession of any such records.

(4) Methods to access, transmit, store, analyze, or purge confidential information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience. Procedures shall be in place to ensure that purged confidential information cannot be misused or placed into active operation without appropriate authorization as provided in this rule. Internet connectivity or remote access tied directly to systems containing confidential information must be secure as provided for in 4 CSR 220-2.085(2)(B).

20 CSR 2220-2.180 Public Records

PURPOSE: This rule establishes standards for compliance with Chapter 610, RSMo as it relates to public records of the State Board of Pharmacy.

(1) All public records of the State Board of Pharmacy shall will be open for inspection and copying by any member of the general public during normal business hours, holidays excepted, except for those records closed pursuant to section 610.021, RSMo. All public meetings of the Board of Pharmacy not closed pursuant to the provisions of section 610.021, RSMo will be open to any member of the public.

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

(3) When a request for inspection of public records is made and the individual inspecting the records requests copies of the records, the board will collect the appropriate fee for costs for inspecting and copying of the records, as outlined in the board’s fee rule, 4 CSR 2220-4.020 20 CSR 2220-4.010. The board may require payment of the fees prior to making available any public records.

(4) When a request for access to public records is made and the custodian believes that access is not required under the provisions of Chapter 610, RSMo, the custodian shall inform the individual or entity making the request that compliance with the request cannot be made, specifying in particular what sections of Chapter 610, RSMo require that the record remain closed. Any such correspondence or documentation of the denial made for access to records shall be copied to the Board of Pharmacy general counsel. Whenever the custodian denies access to the records, the custodian also shall inform the individual requesting the records that s/he may appeal directly to the Board of Pharmacy for access to the records requested. The appeal and all information pertaining to the appeal shall be placed on the meeting agenda of the Board of Pharmacy for its next regularly scheduled meeting. In the event that the board decides to reverse the decision of the custodian, the board shall direct the custodian to so advise the person requesting access to the information and supply the access to the information during regular business hours at the convenience of the requesting party. WE DON’T FOLLOW THIS PROCEDURE CURRENTLY.
(5) The custodian shall maintain a file which will contain copies of all written requests for access to records and responses to the requests. These requests shall be maintained on file with the board for a period of one (1) year and will be maintained as a public record of the board open for inspection by any member of the general public during regular business hours.

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

(A) Federal or state agency documents shall not be released without the written consent of the federal or state agency involved. This is addressed in § 324.017, RSMo. At times, a complaint or investigation documents may be given to a licensee to assist in the investigation or to allow the licensee to respond.


20 CSR 2220-2.300 Record Confidentiality and Disclosure

PURPOSE: This rule establishes requirements for the confidentiality and disclosure of records related to patient care.

(1) Prescription records, physician orders and other records related to any patient care or medical condition(s) of a patient that are maintained by a pharmacy in accordance with section 338.100, RSMo shall be considered confidential. Adequate security shall be maintained over such records in order to prevent any indiscriminate or unauthorized use of any written, electronic or verbal communications of confidential information.

(2) Confidential records shall not be released to anyone except—

   (A) The patient;
   (B) A health care provider involved in treatment activities of the patient;
   (C) Lawful requests from a court or grand jury;
   (D) A person authorized by a court order;
   (E) Any other person or entity authorized by a patient to receive such information;
   (F) For the transfer of medical or prescription information between pharmacists as provided by law;
   (G) Government agencies acting within the scope of their statutory authority; or
   (H) A person or entity to whom such information may be disclosed under 45 CFR Parts 160, 164 and 165 (the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996) or other applicable state/federal law.

(3) This rule does not change or otherwise alter the authority of the board, its inspectors or other authorized designees to review, inspect, copy or take possession of any such records.

(4) Methods to access, transmit, store, analyze, or purge confidential information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience. Procedures shall be in place to ensure that purged confidential information cannot be misused or placed into active operation without appropriate authorization as provided in this rule. Internet connectivity or remote access tied directly to systems containing confidential information must be secure as provided for in 4 CSR 220-2.085(2)(B).

20 CSR 2220-2.600 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 is maintained 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 for establishing 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. NO ONE DOES THIS RIGHT NOW.

(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 is completed 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.


20 CSR 2220-2.675 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 and 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.

(5) 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 who is 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.

(6) 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 does 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.

(7) 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. 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. This is in section (3) and (7)(J)

(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.
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.


SHALL= 6/3
MUST= 4/4

[30% Reduction]

20 CSR 2220-2.800 Vacuum Tube Drug Delivery System

PURPOSE: This rule defines the minimum standards for a vacuum tube drug delivery system utilized in licensed pharmacies.

(1) Vacuum tube systems are for use in the delivery of drugs to the patient or his/her agent.
   (A) Any drug delivery system that utilizes a vacuum tube to deliver drugs outside of a licensed pharmacy must be designed and engineered in such a way as to ensure security of all drugs and that drugs are delivered correctly and efficiently to the intended recipient.
   (B) Only systems that are dedicated for the delivery of drugs from a location within a licensed pharmacy to another location specific for drug delivery and are not connected, combined or attached to other systems shall may be used. Multiple or switchable stations where the delivery of drugs could occur at more than one destination outside of the pharmacy are prohibited.
   1. When the pharmacy is closed or there is no pharmacist on duty, the vacuum tube system must be turned off and no drugs shall be delivered to consumers during these time periods.
   (C) Any pharmacy, which cannot maintain a direct and identifiable line of sight with the consumer, must maintain a video camera and audio system to provide for effective communication between pharmacy personnel and consumers. It must be a system that will allow for the appropriate exchange of oral as well as written communications to facilitate patient counseling and other matters involved in the correct transaction or provision of drugs.
      1. Video monitors used for the proper identification of persons receiving prescription drugs shall be a minimum of twelve inches (12”) wide.
      2. Both the video monitor and the audio system must be in good working order or operations utilizing the vacuum tube system shall cease until appropriate corrections or repairs are made to the system(s).
      3. Backlighting or other factors that may inhibit video or audio performance must be taken into account when using such systems to identify recipients of prescription drugs. Positive identification of recipients must be made before any drug is delivered.
(2) All vacuum tube delivery systems installed after September 1, 1998, shall comply with the minimum standards set forth in this rule. Any vacuum tube delivery system already installed in a pharmacy prior to September 1, 1998, will not be required to comply with this rule; except that, should the vacuum tube delivery system or any part thereof require replacement, change, or upgrading after September 1, 1998, the system or any part of the system being replaced, changed or upgraded shall comply with the minimum standards set forth in this rule. This exemption does not relieve a pharmacy of its duty to maintain adequate security measures as required by 4 CSR 220-2.010(1)(H) or the rules of the Board; nor does it relieve pharmacists from their duty to provide patient counseling as required by 4 CSR 220-2.190.


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" does 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. 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.


Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 3—Negative Generic Drug Formulary

SHALL= 7/2
MUST= 1/0

[ 75% REDUCTION]

20 CSR 2220-3.011 Generic Drug Formulary Substitution

PURPOSE: The purpose of this rule is to comply with the section 338.057, RSMo (1986), which directs the Department of Economic Development to publish a list of drug products for which substitution, by a pharmacist shall not be permitted. Noting that there are a number of drug products within a specific drug product category that have been proven bioequivalent and bioavailable to the Federal Food and Drug Administration, the Department of Economic Development has delineated within a particular drug product category those drugs that may be substituted. The list is dual in nature. There are certain drugs where substitution will not be permitted and there are certain drug products where qualified substitution will be allowed, again only if the drug and manufacturer is specifically designated in the list establishes requirements for generic substitution.

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

(1) If a written prescription is involved, the prescription form used shall have two (2) signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words: “Dispense as Written.” Under the line at the left side shall be clearly printed the words “Substitution Permitted.” The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one (1) of these lines.

(2)(1) All pharmacists and dispensing physicians should be warned that any drug product not holding an approved New Drug Application or Abbreviated New Drug Application may not be used as a substitute in the state of Missouri without the dispenser assuming some personal liability.
(3)(2) A pharmacist shall not substitute drug products that are rated as therapeutically inequivalent to other pharmaceutically equivalent products as listed in the latest edition or cumulative supplement of The Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Government, Department of Health and Human Services.

(4) Any drug that is manufactured by an innovator company under a supplement to their New Drug Application (NDA) for that specific drug may apply to the Missouri Board of Pharmacy for consideration as a drug that is generically equivalent to the innovator product. A written request for such consideration must be accompanied by an affidavit or other acceptable documentation from the Food and Drug Administration (FDA) attesting to the equivalency of the generic product to the innovator product. Once the Missouri Board of Pharmacy determines that the two products are considered generically equivalent under state law, an appropriate notation will be made in the next revision of the Generic Drug Formulary.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 5—Drug Distributor

20 CSR 2220-5.010 Drug Distributor Advisory Committee

PURPOSE: This rule establishes operating guidelines for the drug distributor advisory committee.

(1) As authorized in section 338.140.4, RSMo, an advisory committee, composed of five (5) members, one (1) of whom shall be a representative of pharmacy, but who shall not be a member of the pharmacy board, three (3) of whom shall be representatives of wholesale drug distributors, as defined in section 338.330, RSMo, and one (1) of whom shall be a representative of drug manufacturers, shall be appointed by the State Board of Pharmacy. This language duplicates the statute.

(2) Appointments to the drug distributor advisory committee authorized by section 338.140.4, RSMo, shall be made by the president of the board.

(A) Except for the initial committee appointments, each appointment shall be for a term of five (5) years. Beginning with the first committee appointments, the terms will be staggered so that one (1) term will expire each year after that.

(B) No appointment shall become effective until approved by the board. Each candidate shall meet with the board prior to any decision by the board to confirm. This meeting will be held in order for the board to review the candidate’s credentials and to familiarize him/her with board personnel and advisory committee responsibilities.

(C) Terms of new committee members shall commence on July 1, unless the appointment is to fill an unexpired term.

(3) The advisory committee shall organize by the election of a chairman and vice-chairman who shall hold their offices for one (1) year and until their successors shall have been elected and qualified. A majority of the committee shall constitute a quorum for the transaction of business.

(4) The advisory committee shall review and make any recommendations to the board on the merit of all rules dealing with pharmacy distributors, wholesale drug distributors and drug manufacturers which are proposed by the board.

(A) The advisory committee shall maintain minutes of all meetings held.

(B) Any recommendations made by the advisory committee concerning proposed regulations shall be noted and explained in the minutes which will be provided to the board at an open session meeting of the board. The advisory committee may provide other documentation, reports or correspondence to the board when necessary or appropriate.
(C) Any official recommendations to be made from the committee to the board must be initiated by a motion that receives a majority vote in favor by the attending committee members. This motion and vote shall be recorded in the minutes.

(D) The board will review any recommendations made by the advisory committee and will provide a response to the committee if any action is taken or modifications are made to a proposed regulation. In addition, the board shall note in the Missouri Register the dates and a summary of any recommendations made by the advisory committee on a proposed rule and report any responses that are made to those recommendations from the board.

(5) Committee members shall be reimbursed for all reasonable and necessary expenses for attending committee meetings as authorized by law. However, only expenses incurred within Missouri will routinely be reimbursed. No request for the compensation of expenses provided in this rule shall be processed for payment unless sufficient funds are available for that purpose within the appropriation of the State Board of Pharmacy.


20 CSR 2220-5.020 Drug Distributor Licensing Requirements

PURPOSE: This rule defines terms and requirements for the lawful licensure of drug distributors.

(1) A “wholesale drug distributor” is defined in section 338.330(3), RSMo. No wholesale drug distributor with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also includes, but not be is not limited to, notification from the board by mail or electronic transmission.

   (A) A wholesale drug distributor is further defined as anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

   (B) Licensure and/or registration as a wholesale drug distributer is not required for activities described below—

   1. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, transfer, or trade a drug for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. The amount sold, purchased, transferred, or traded shall may not exceed five percent (5%) of the pharmacy’s total gross prescription sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total drug purchases;

   2. The sale, purchase, or trade of blood and blood components intended for transfusion and any other exemptions as provided for in Chapter 338, RSMo;

   3. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, or trade a drug by a Missouri licensed pharmacy that does not exceed five percent (5%) of the pharmacy’s total gross sales. For purposes of this section, total gross sales shall be calculated based on the pharmacy’s total annual prescription drug sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total drug purchases;
4. The sale, purchase, transfer, or trade of a drug or offer to sell, purchase, transfer, or trade a drug among hospitals or by a hospital to a healthcare entity under the same common control or ownership as the hospital. “Common control or ownership” means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership, stock, voting rights, contract, or otherwise. For purposes of this rule, a “hospital” shall be limited to a hospital as defined by Chapter 197, RSMo, or a hospital operated by the state;

5. The storage or distribution of drugs by a local, state, or federal facility that are received from the Strategic National Stockpile or the state stockpile for the purpose of providing those drugs in an emergency situation as authorized by a state or federal agency;

6. The sale, purchase, transfer, or trade of a prescription drug to alleviate a temporary shortage of a prescription drug that is in limited supply or unavailable due to delays in or interruption of supply. Drugs sold, purchased, transferred, or traded pursuant to this section shall only be sold, purchased, transferred, or traded directly from an importer or manufacturer authorized by or registered with the United States Food and Drug Administration (FDA) to import or manufacture the drug that is unavailable or in short supply. In addition, sales, purchases, transfers, or trades shall be limited to the period of shortage and to the drug that is unavailable or in limited supply. Documentation of FDA authorization or registration shall be maintained in the licensee’s or recipient’s records; and

7. The sale, purchase, transfer, or trade of a drug between a Missouri licensed pharmacy and a non-resident pharmacy that is located in and licensed by another state or United States territory. The total amount of drug sold, purchased, transferred, or traded by the Missouri-licensed pharmacy pursuant to this subsection shall not exceed five percent (5%) of the pharmacy’s total annual prescription drug sales. Missouri pharmacies receiving drugs pursuant to this section from a non-resident pharmacy shall maintain the following records for two (2) years from the date of sale, purchase, transfer, or trade:

A. Proof the non-resident pharmacy holds a current pharmacy license in the state or territory from which the drug is shipped or distributed; and

B. An invoice record which documents the name and address of the non-resident pharmacy, the date of sale, purchase, transfer, or trade, and the name, strength, and quantity of the drug received. The pharmacies shall also comply with all applicable controlled substance requirements.

(C) Wholesale drug distributors shall inform the board of their current FAX number, any change in FAX number, and/or the fact that the wholesale drug distributor does not have a working FAX. In the event a wholesale drug distributor notifies the board that the wholesale drug distributor does not have a working FAX, notification from the board will be made to the wholesale drug distributor by first class mail. For the purposes of this rule, such notification by mail shall be considered effective three (3) days after mailing and shall have the same effect as notification by FAX.

(D) Failure to receive notification from the board shall not be a defense to violations of section (1) of this rule when the wholesale drug distributor has failed to comply with the requirements of subsection (1)(C) of this rule.

(2) All licenses for the operation of a drug distributor shall expire on the date specified by the director of the Division of Professional Registration by appropriate rule.
(3) Drug distributor licenses shall be issued on the application of the owner. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant. The application must be signed by:

(A) For corporations, an officer of the corporation;
(B) For partnerships, a partner;
(C) For limited liability partnerships, a general partner; and
(D) For limited liability companies, a member.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along with the appropriate fees before any license is issued or renewed. Information required on the application shall include:

(A) The name, full business address, electronic facsimile transmission number (FAX), and telephone number of the licensee;
(B) All trade or business names used by the licensee;
(C) The address, telephone number, and the name of the manager in charge for each facility used by the licensee for the storage, handling, and distribution of prescription drugs;
(D) The type of ownership or operation;
(E) The name(s) of the owner, operator, or both, of the licensed entity, including:
   1. If a person, the name of the person;
   2. If a partnership, the name of each partner and the name of the partnership;
   3. If a corporation, the name of the corporate president, vice president, secretary, treasurer, chief executive officer, board of directors, and senior vice presidents or their equivalents, the corporate name(s), and the name of the state of incorporation; and
   4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
(F) The name of the manager-in-charge who meets the requirements as set forth in 20 CSR 2220-5.030(2); a complete notarized manager-in-charge affidavit of the license application; and a history of employment/occupations and offices held during the past seven (7) years; and
(G) An application for a wholesale or pharmacy drug distributor license will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(5) When a drug distributor changes ownership, the original license becomes void on the effective date of the change of ownership. Before any new business entity resulting from that change opens a facility as a drug distributor, it must obtain a new license from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license shall be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(A) A change of ownership of a drug distributor facility owned by a sole proprietor is deemed to have occurred when—
   1. The business is sold and the sale becomes final;
   2. The proprietor enters into a partnership with another individual or business entity; or
3. The proprietor dies; provided, however, that the proprietor’s estate may continue to operate the drug distributor facility for a period of no more than one (1) year and only so long as appropriate fees are paid.

(B) If a corporation owns a drug distributor facility, it is not necessary to obtain a new license if the owners of the stock change. If a limited liability partnership or a limited liability company owns a drug distributor company, it is not necessary to obtain a new license if the partners or members of the company change, as long as the partnership or company is not dissolved by that change. It is necessary to file written notice with the Board of Pharmacy within thirty (30) days after a change occurs of twenty-five percent (25%) or more in the ownership of corporation stock, or in partners in a limited liability partnership, or in members of the limited liability company. This notification must be in writing and certified. However, when a corporation, limited liability partnership, or limited liability company begins ownership of a drug distributor company or ceases ownership of a drug distributor company, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent, or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon this approval and receipt of a change of location fee, the board shall issue a license authorizing operation of a facility at the new location and the license shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

(7) Separate licenses are required for each drug distribution site owned or operated by a drug distributor as defined in section 338.330, RSMo.

(8) The Board of Pharmacy may grant a temporary license to a wholesale or pharmacy drug distributor to allow for the conduct of business within the state until a determination by the board is made on the issuance of a permanent license.

(A) Temporary licenses are valid until the board shall find that the applicant meets or fails to meet the requirements for regular licensure or one (1) year, whichever is less.

1. The board will consider, at a minimum, the following factors in reviewing the qualifications of persons who apply or renew as a drug distributor:

   A. Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

   B. 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;
C. The applicant’s past experience in the manufacture or distribution of prescription drugs, including controlled substances;
D. The applicant furnishing false or fraudulent material in any application made in connection with drug manufacturing or distribution;
E. Suspension, revocation, or probation by federal, state, or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
F. Compliance with licensing requirements under previously granted licenses, if any; and
G. Requirements to maintain or make available, or both, to the board or the federal, state, or local law enforcement officials those records required under this section are followed.

2. If an applicant for a license in any way fails to provide information as requested by the board or does not cooperate with requests and inquiries made by the board or provides false or misleading information to the board and the temporary license expires or is denied, all fees paid by the applicant shall be forfeited.

3. During the period of time that a temporary license is in effect, the applicant may conduct business in this state as a drug distributor as long as all state and federal laws governing drug distribution are followed and no action that results in professional misconduct as outlined in section 338.055, RSMo is documented.

4. If it is determined by the board that a permanent license is to be denied to an applicant, a denial notification letter shall be sent to the applicant. The temporary license will be considered invalid ten (10) days after notification is sent to the applicant by certified mail.

(B) A license must be posted in a conspicuous place in the facility to which it is issued.

(9) Each licensed corporate wholesale distributor located outside of this state that distributes drugs in this state shall designate a registered agent in this state for service of process. Any licensed corporate wholesale distributor that does not designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal process in any action or proceeding against any licensed corporate wholesale distributor growing out of or arising from such distribution. Service of process may be accomplished as authorized by law.


SHALL= 9/6
MUST= 2/2

[27% Reduction]

20 CSR 2220-5.025 Termination of Business as a Drug Distributor

PURPOSE: This establishes guidelines for the termination of business as a drug distributor.

(1) A licensed drug distributor who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the license and shall include the following information:
   (A) The name, address, license number and effective date of closure;
   (B) The name, address and license number of the entity to which any of the stock/inventory will be transferred; and
   (C) The name and address of the location to which records, required to be maintained by law, have been transferred;
      1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board;
      2. Any records that are transferred to a licensed drug distributor or pharmacy must be maintained in accordance with record requirements as set forth in 4 CSR 220-5.030 20 CSR 2220-5.030.

(2) The licensee terminating business may transfer all drugs and records in accordance with the following:
   (A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the drug distributor terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer;
   (B) A drug distributor terminating business shall may not transfer misbranded, outdated or adulterated drugs, except for purposes of proper disposal; and
   (C) Upon the actual termination of business, the license of the drug distributor shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a drug distributor.
(4) The termination date is the date on which the drug distributor licensee ceases to do business as a distributor as defined in section 338.330(1), (2) or (3), by Chapter 338, RSMo, in the state of Missouri.


20 CSR 2220-5.050 Out-of-State Distributor License/Registration Requirements

PURPOSE: This rule establishes guidelines for license/registration procedures for out-of-state drug distributors.

(1) Out-of-state wholesale drug distributors or out-of-state pharmacy distributors may be licensed, as required by sections 338.210—338.370, RSMo, by reciprocity if they—
   (A) Possess a valid license in good standing in the state or foreign jurisdiction in which they are located pursuant to legal standards comparable to those which must be met by a distributor of this state as prerequisites for obtaining a distributor license under the laws of this state; and
   (B) Are located in a state or foreign jurisdiction which extends reciprocal treatment under its own laws to a wholesale distributor of this state.

(2) Out-of-state wholesale drug and pharmacy distributors shall not ship, mail or deliver prescription drugs into Missouri without first obtaining a license from the Missouri Board of Pharmacy.
   (A) In order for an out-of-state wholesale drug or pharmacy distributor to maintain a license, it must comply with each of the following:
      1. Maintain in good standing a license from the state or foreign jurisdiction in which the nonresident distributor is located provided that a license is issued by that state or foreign jurisdiction;
      2. Submit an application as provided by the board for licensure in compliance with sections 338.333 and 338.337, RSMo and with 4 CSR 220-5.020 20 CSR 2220-5.020;
      3. Pay all appropriate fees;
      4. Submit a copy of the state or foreign jurisdiction license or its equivalent from the state or foreign jurisdiction in which the distributor is located provided that a license is issued by that state or foreign jurisdiction;
      5. Submit a copy of the state or foreign jurisdiction and federal controlled substance registrations from the state or foreign jurisdiction in which they are located, if controlled substances are to be shipped into Missouri; and
      6. Submit copies, when requested by the board, of any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state or foreign jurisdiction in which it is located concerning the operation of an out-of-state drug or pharmacy distributor for review of compliance with state, federal or foreign jurisdiction drug laws.
(B) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state or foreign jurisdiction that licenses and regulates out-of-state drug or pharmacy distributors for the purpose of investigating complaints against distributors located in Missouri or the sharing of information and investigative reports, as long as the other state or foreign jurisdiction will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.

(3) An exemption to licensure is allowed when an out-of-state wholesale drug distributor supplies a drug to another drug distributor licensed in this state in an emergency situation. The amount of the distribution allowed must be confined to the emergency situation and the total amount of distribution for emergency situations must not exceed one percent (1%) of the total annual gross sales of the unlicensed distribution site.

(4) Registration in lieu of licensure may be sought by an out-of-state drug distributor when the following provisions exist:
   (A) The out-of-state drug distributor is a drug manufacturer;
   (B) The manufacturing facility is used for both the production (manufacture) and distribution of legend drugs;
   (C) The site has been inspected with a satisfactory rating by the Food and Drug Administration within the last two (2) years. Inspections of these facilities must comply with all standards and requirements as outlined in 4 CSR 220-5.040 20 CSR 2220-5.040;
   (D) The state in which the manufacturing facility is located issues a license and the license is current and in good standing; and
   (E) The out-of-state distributor who qualifies for registration must complete an application as provided by the board and submit it along with a filing fee of ten dollars ($10).

1. The board shall provide, on an annual basis, a registration renewal form to all registered out-of-state distributors.
2. In order for a registration to remain in good standing and in effect, the renewal must be returned to the Division of Professional Registration—registration must be renewed biennially by an expiration date that is specified by the director of the division—Division of Professional Registration by appropriate rule.
3. In order for a registration to be renewed, it must comply with all the provisions for registering as a drug distributor facility as outlined in section 338.337, RSMo and this rule.
4. Each renewal application must be submitted along with a filing fee of ten dollars ($10).


Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 5—Drug Distributor

SHALL= 7/1  
MUST= 1/0

[87.5% Reduction]

20 CSR 2220-5.060 Controlled Substance Reporting

PURPOSE: This rule defines requirements for reporting the distribution of controlled substances from drug and pharmacy distributors to persons and facilities that are registered with the Federal Drug Enforcement Administration.

(1) Wholesale drug and pharmacy distributors that distribute Schedule II products and Schedule III narcotics Automation of Reports and Consolidated Orders (ARCOS products) shall provide a manual or electronic listing of those all drug products and controlled substances distributed by the licensee within the state to the board on a quarterly basis when requested to do so by the board or the Board’s authorized designee. In addition, wholesale drug and pharmacy distributors that distribute controlled substances within the state shall provide up to a twenty-four (24) month retrospective listing of all controlled substances (Schedule II through Schedule IV) distributed within the state or to a specific location to the board when requested to do so by the board. The board shall submit the request thirty (30) days in advance of the information requested. Reports must be submitted to the board either on hard copy in typewritten form or by electronic media. If electronic media is used in providing the reports, it shall be provided in one (1) of the following formats.

(A) If an electronic tape is used, it shall be an IBM 9 track, labeled or nonlabeled, 1600 or 6250 bits per inch (bpi);

(B) If a diskette is used, it shall be either a MacIntosh 400K or 800K; MS-DOS 5 1/4" 360K or 1.2 meg; MS-DOS 3 1/2" 720K or 1.44 meg; or an IBM 8" diskette; or

(C) If a cartridge is used, it shall be a 1/2" tape, 3480 Compatible.


20 CSR 2220-6.030 Provision of Drug and/or Medical Information

PURPOSE: The purpose of this rule is to define requirements for the provision of drug and/or medical information by pharmacists.

(1) Section 338.095.3., RSMo provides in part that a pharmacist may lawfully provide prescription or medical information to a licensed health care provider or his/her agent who is legally qualified to administer medications and treatments and who is involved in the treatment of the patient. The information may be derived through direct contact with a prescriber or through a written, agreed upon protocol or standing prescription order from an authorized prescriber.

(2) Information transfers as described in section (1) may take place within any practice setting as long as the pharmacist maintains an active license with the Board of Pharmacy.

(3) Information transfers between two (2) licensed pharmacists may occur as long as the pharmacist receiving that information documents in a uniform and readily retrievable fashion, the identity of the pharmacist providing the information transfer, the origin of his/her authority to provide the drug or medical information, the date and the identity of the receiving pharmacist.

(4) When a transfer of prescription information for the purpose of filling an original prescription occurs, all provisions of 4 CSR 220-2.120 must be followed, except for subsection (1)(C) and paragraphs (2)(B)4.–6. Staff recommends moving this subsection to 2.120.

(5) Any laws governing prescription records, dispensing procedures and controlled substances must be adhered to when a transfer of prescription information for the purpose of filling an original prescription occurs.


20 CSR 2220-6.055 Non-Dispensing Activities

PURPOSE: This rule establishes procedures and requirements for the performance of non-dispensing activities outside of a pharmacy.

(1) Pursuant to section 338.220, RSMo, a pharmacist may perform the following non-dispensing activities outside of a licensed pharmacy:
   (A) Patient counseling/education, as authorized by Missouri law, provided the pharmacist shall be obligated to comply with 20 CSR 2220-2.190, when applicable;
   (B) Obtain patient history/information;
   (C) Review patient records/medical histories;
   (D) Patient assessment/evaluation, as authorized by Missouri law;
   (E) Billing and insurance claim submissions/review;
   (F) Drug utilization review;
   (G) Assess health plan and medication eligibility/coverage;
   (H) Pharmacy compliance audits/evaluations;
   (I) Administer drugs, vaccines, or biologicals, as authorized by law and the rules of the board;
   (J) Peer review/peer consultations;
   (K) Review, select, and develop formularies or plan/practice guidelines;
   (L) Review compliance with benefit guidelines;
   (M) Manage inventory, including purchasing and ordering;
   (N) Manage/review information systems;
   (O) Patient medication review;
   (P) Consultation with other health care professionals;
   (Q) Patient referrals;
   (R) Prescription order entry/review, provided that a pharmacist shall only be authorized to may only accept a prescription on the premises of a Missouri licensed pharmacy, as required by section 338.095.5, RSMo; and
   (S) Medication therapy management, pursuant to and as authorized by Chapter 338, RSMo, and the rules of the board.
(2) Confidentiality. A pharmacist performing non-dispensing activities pursuant to this rule shall comply with all applicable state and federal confidentiality laws and regulations and shall provide sufficient storage and security for confidential documents and electronic data processing hardware. In addition, data processing systems must utilize sufficient security software to ensure confidentiality and prevent unauthorized access. Any breach in the security or confidentiality of the data processing systems or confidential documents shall be documented and reported to the board in writing within seven (7) days of the breach.

(3) Notwithstanding any other provision of this rule, a pharmacist shall not meet with patients in the pharmacist’s residence or living quarters.

(4) A pharmacist performing non-dispensing activities pursuant to this rule shall ensure compliance with Chapter 338, RSMo, and the rules of the board at all times. Nothing in this rule shall be construed to eliminate or otherwise exempt any pharmacist from the record-keeping, confidentiality, or security requirements otherwise imposed by Chapter 338, RSMo, or the rules of the board. Violations of this section shall constitute grounds for discipline.

(5) This rule shall not be construed to authorize a pharmacist to conduct the unauthorized practice of medicine or to conduct any activity for which a license is required pursuant to Chapters 330, 331, 332, 334, or 337, RSMo.

(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to may only work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.


Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 7—Licensing

SHALL= 8/3
MUST= 0

20 CSR 2220-7.010 General Licensing Rules

PURPOSE: This rule defines terms used and general requirements governing board licensing activities as used in Chapter 7.

(1) Definitions.
(A) ACPE—Accreditation Council for Pharmacy Education.
(B) Accredited school/college of pharmacy—a school or college of pharmacy accredited by ACPE.
(C) Approved school/college of pharmacy—a Missouri school or college of pharmacy whose curriculum, physical equipment, course of instruction, and teaching personnel conform to ACPE standards and specifications and that has been recognized by the board as an approved school/college for pharmacy practice experience pursuant to 20 CSR 2220-7.027.
(D) Board—the Missouri State Board of Pharmacy.
(E) Foreign school/college—a school/college of pharmacy that is not located in the United States or a United States territory.
(F) MPJE—Multistate Pharmacy Jurisprudence Examination.
(G) NABP—National Association of Boards of Pharmacy.
(H) NAPLEX—North American Pharmacist Licensure Examination.

(2) An application shall not be considered filed if it has to be returned to the applicant for an incorrect or missing fee, an incomplete or missing college affidavit, or an incomplete or missing signature or notarization. In this instance, the application will be returned to the applicant and will not be deemed filed until it has been returned with all corrections made. An application shall be deemed invalid if the applicant fails to submit all information required to complete the application within six (6) months after the application is received by the board.

(3) No duplicate license or registration shall be issued except upon the return of the original or upon an affidavit from the licensee that the certificate has been lost, stolen, or destroyed. The duplicate certificate, license, or registration fee shall accompany the affidavit.

(4) Except as otherwise provided, all licensing and registration fees required by the rules of the board are nonrefundable.

(5) A copy of proof of licensure/registration from the board’s official website may be used as proof of licensure by an applicant until a hard copy license/registration has been received from the board.
(6) Failure to receive a renewal notice or application from the board shall not excuse the licensee/registrant from any renewal requirements established by Chapter 338, RSMo, or by rule of the board.

(7) Except as otherwise determined by the board, a pharmacist applicant shall be eligible for a temporary authorization letter to practice pharmacy pending final board approval of the applicant’s pharmacist license if the applicant has submitted a complete pharmacist application to the board and has successfully passed all required examinations (NAPLEX and/or MPJE).

   (A) Applicants not eligible for a temporary authorization letter may apply for a technician registration pursuant to the rules of the board. Applicants working as a technician shall be under the direct supervision of a licensed pharmacist at all times when any functions related to section 338.010, RSMo., are performed and shall comply with all Missouri requirements for pharmacy technicians.

   (B) Applicants required to apply for a technician registration will not be required to provide Additional fingerprints if all fingerprinting requirements have previously been fulfilled and are not required if the applicant’s fingerprints were submitted to the Board less than six (6) months before the board’s receipt of the application for technician registration.


20 CSR 2220-7.025 Intern Pharmacist Licensure

PURPOSE: This rule establishes requirements for intern pharmacist licensure and pharmacy practice experience.

(1) The provisions of this rule shall be applicable to individuals seeking to earn pharmacy practice experience in Missouri.

(2) Requirements for Licensure. Every person who desires to gain pharmacy practice experience in Missouri shall first apply for an intern pharmacist license. Application for licensure shall be made on forms provided by the board and shall be accompanied by the application fee. To be eligible for licensure, the applicant shall—
   (A) Be currently enrolled in or graduated from a school or college of pharmacy that is accredited by the Accreditation Council for Pharmacy Education (ACPE); and
   (B) Submit proof of fingerprinting as required by 20 CSR 2220-7.090.

(3) Site/Preceptor Approval. After licensure, an intern pharmacist shall only be authorized to earn pharmacy practice experience in a site approved by the board and under the supervision of a board-approved preceptor. Requests for site and preceptor approval shall be submitted on a form provided by the board. The board may request additional information, interview program participants, or complete site inspections before a decision on an application is made. The intern pharmacist will receive confirmation from the board office noting approval of the site and preceptor and a start date after which pharmacy practice experience may be counted. In no event shall an intern pharmacist be credited for hours earned prior to being licensed by the board as an intern pharmacist.
   (A) Site Approval. The board shall only approve a site for pharmacy practice experience if the site holds a pharmacy license from a United States (U.S.) state or territory and such license is not under disciplinary action with the licensing entity.
   (B) Special Sites. An individual or entity/facility may petition the board to approve an entity/facility that is not a licensed pharmacy for purposes of intern training as a special site if the pharmacy practice experience to be earned complies with 20 CSR 2220-7.030(1)(A)3. Requests shall be made on a form provided by the board and shall include a detailed description of the pharmacy practice experience to be earned.
(C) Preceptor Approval. To be eligible for approval, a supervising preceptor shall hold a pharmacist license from a U.S. state or territory and such license is active and not under disciplinary action in such U.S. state or territory. An individual/entity may petition the board to approve a preceptor that is not a Missouri-licensed pharmacist on a form provided by the board. The board may, in its discretion, approve a non-pharmacist preceptor if the preceptor is sufficiently qualified to train interns in the proposed pharmacy practice experience area(s) and the experience to be earned complies with the provisions of 20 CSR 2220-7.030(1)(A)3.

(D) Students enrolled in an approved school/college of pharmacy shall be authorized to earn experience as part of their school/college curriculum at any site or with any preceptor approved by the board for the school/college. However, students desiring to earn pharmacy practice experience outside of, or in addition to, the training/experience required as part of the curriculum of an approved school/college of pharmacy (i.e., non-school related summer employment) shall comply with the provisions of this rule for the additional hours earned and shall separately request prior approval by the board of the site/preceptor to be used.

(4) Calculation of Hours. An intern pharmacist shall only be given credit for hours earned in activities related to the practice of pharmacy as determined by the board or connected with pharmaceutical or patient-centered care through the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices pursuant to prescription orders; the proper and safe storage of drugs and devices and the maintenance of proper records of them; or consultation with patients and other health care practitioners about the safe and effective use of drugs and devices.

(A) Except as otherwise provided herein, an intern pharmacist shall only receive credit for pharmacy practice experience that is earned after the date of licensure as an intern, at an approved site and under the supervision of an approved preceptor.

(B) Certification of Hours. An intern pharmacist shall file a Preceptor’s Affidavit of Internship Hours at the completion of his/her pharmacy practice experience on a form provided by the board. The report shall identify the pharmacy practice experience hours earned at each approved training site and shall be signed by the supervising preceptor. No credit shall be granted for hours not reported to the board. In lieu of the preceptor affidavit, an approved school/college of pharmacy shall certify to the board the pharmacy practice experience earned by each student as part of the required curriculum. Certification shall be submitted by the approved school/college of pharmacy upon the student’s graduation or within thirty (30) days after the student is no longer enrolled in the pharmacy school/college.

(C) An intern pharmacist shall not be allowed or granted more than forty-eight (48) hours of intern credit each week. An intern pharmacist shall not be credited for hours earned while practicing/working as a pharmacy technician.

(D) The board shall not certify or verify any pharmacy practice experience gained in Missouri unless the pharmacy practice experience complies with the requirements of this rule. Additionally, the board will not verify or certify hours earned by a student if the board does not receive certification from the preceptor or the school/college documenting the hours required by this rule.
(5) Change of Intern Location/Preceptor. Except as provided for students of an approved school/college of pharmacy, an intern pharmacist shall promptly notify the board of a change in intern site/preceptor and request approval of the site/preceptor to be used. If approved, the intern pharmacist shall not be credited for hours earned more than ten (10) days prior to the date the approval request is filed with the board. No credit shall be granted for hours earned if the request for site/preceptor approval is subsequently disapproved by the board.

(6) Intern pharmacists shall file an application to renew their intern pharmacist license between October 1 and December 31 of each even-numbered year. Applications shall be made on a form provided by the board and accompanied by the renewal fee.


SHALL = 15/10
MUST = 2/2

[29% Reduced]

20 CSR 2220-7.027 Approved Missouri Schools/Colleges of Pharmacy

PURPOSE: This rule establishes requirements for approval of pharmacy practice experience earned as part of the curriculum of a Missouri school/college of pharmacy.

(1) Upon request, the board may approve a Missouri school/college of pharmacy for purposes of providing pharmacy practice experience to enrolled students. To be eligible for approval, the school/college of pharmacy shall be located in Missouri and shall—
   (A) Be accredited by the Accreditation Council for Pharmacy Education (ACPE);
   (B) Require as part of the school/college curriculum or training, a minimum of one thousand five hundred (1,500) hours of pharmacy practice experience in activities related to the practice of pharmacy as determined by the board or connected with pharmaceutical or patient-centered care through the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices pursuant to prescription orders; the proper and safe storage of drugs and devices and the maintenance of proper records of them; the administration of immunizations; or consultation with patients and other health care practitioners about the safe and effective use of drugs and devices;
   (C) Submit a list of all preceptors and sites that will be used within the school/college curriculum for pharmacy practice experience; and
   (D) Submit the school’s/college’s policies and procedures for obtaining practice experience for board approval. The policies and procedures shall include policies/procedures for student training, approving sites/preceptors, and monitoring practice experience activities.

(2) The board may, in its discretion, disapprove a Missouri school/college of pharmacy if the policies or procedures do not comply with the pharmacy practice experience requirements of this rule or Chapter 338, RSMo. The policies and procedures shall be resubmitted annually to the board for approval or as otherwise requested by the board.

(3) Site/Preceptor Approval. An approved school shall submit to the board for approval a list of all preceptors and sites that will be used within the school’s curriculum for pharmacy practice experience. Except as otherwise provided in section (5) of this rule, sites/preceptors must be approved by the board before the site or preceptor can be used. Once approved, intern pharmacists shall be authorized to may earn pharmacy practice experience required by an approved school’s curriculum/training requirements at any site or with any preceptor approved by the board for the student’s school/college. To be eligible for approval, sites and preceptor approval shall meet the requirements of 20 CSR 2220-7.025(3).
(4) Exemptions. An approved school/college may file a request with the executive director to temporarily approve a site/preceptor if an approved site/preceptor is anticipated to be unavailable for a period likely to exceed seven (7) days, transfer of the intern pharmacist is deemed necessary to ensure compliance with state/federal law, or the intern pharmacist is unable to gain appropriate pharmacy practice experience in the site or under the preceptor previously approved by the board and an alternative placement with an approved site/preceptor is not reasonably available.

(A) The executive director may approve a temporary site/preceptor request if the proposed pharmacy practice experience meets the requirements of this rule. Approval requests shall be filed on a form provided by the board and shall detail the grounds for the request and certify that the site/preceptor meets the requirements of this rule.

(B) To be eligible for approval, the temporary site shall be licensed as a pharmacy in a United States (U.S.) state or territory and the designated preceptor shall be licensed as a pharmacist in a U.S. state or territory. The pharmacist and pharmacy licenses must respectively be active and not under disciplinary action with the board.

(C) Intern pharmacists shall may only receive credit for pharmacy practice experience earned from the date of approval by the executive director. No credit shall be given for hours earned if the board subsequently disapproves the site/preceptor.

(5) Certification of Hours. An approved school/college shall certify the pharmacy practice experience earned by a student to the board upon the student’s graduation or within thirty (30) days after the student is no longer enrolled in the pharmacy program. The board will not verify or certify hours earned by a student as part of the curriculum of a recognized school/college if the board does not receive certification from the school/college documenting the hours earned. An intern pharmacist shall not be granted credit for hours earned while practicing/working as a pharmacy technician.


Shall = 20/13
Must = 2/2

[31.8% Reduced]

20 CSR 2220-7.030 Pharmacist Licensure by Examination

PURPOSE: This rule establishes licensure requirements for examination applicants that have graduated from an accredited college/school of pharmacy.

(1) Examination Applications.
(A) Graduates of a college/school of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE) or an equivalent federally-recognized accrediting body may apply to the board for licensure as a Missouri pharmacist by examination. Applications shall be submitted on forms provided by the board with the examination application fee which is non-refundable. The application shall be notarized and shall include:

1. Satisfactory evidence that the applicant has graduated from an accredited school/college of pharmacy that meets the requirements of this rule;
2. Proof of fingerprinting as required by 20 CSR 2220-7.090; and
3. Proof of one thousand five hundred (1,500) hours of pharmacy practice experience in activities related to the practice of pharmacy as approved by the board or connected with pharmaceutical or patient-centered care through the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices pursuant to prescription orders; the proper and safe storage of drugs and devices and the maintenance of proper records of them; the administration of immunizations; or consultation with patients and other health care practitioners about the safe and effective use of drugs and devices. Pharmacy practice experience earned in another state must be certified directly to the board from the state or governmental pharmacist licensing entity where the hours were earned.

(B) The board shall review the application and determine the candidate’s eligibility to test. Applications shall be deemed incomplete until all requirements of this rule have been met. All application fees shall be non-refundable.

(2) Test Scheduling. When an application has been completed, the board shall notify the applicant if he/she is eligible for the North American Pharmacist Licensure Examination (NAPLEX) and/or the Multistate Pharmacy Jurisprudence Examination (MPJE) automated examinations. If eligible, the applicant shall schedule testing dates for both the NAPLEX and MPJE, as required by the National Association of Boards of Pharmacy (NABP). The applicant shall satisfy all testing and scheduling requirements established by NABP and shall be responsible for completing any necessary application(s) and payment of fee(s) for scheduling/taking the examination(s).
(A) To avoid forfeiture of eligibility, the applicant must take the examination(s) within three hundred sixty-five (365) days after having been determined eligible by the board for examination. If the applicant does not take the examination within three hundred sixty-five (365) days, the applicant shall be required to reapply to the board for examination/licensure and again pay the examination application fee.

(B) A determination by the board that an applicant is eligible for examination does not guarantee that the applicant will be issued a Missouri pharmacist license. The board reserves the right to deny an applicant for licensure that has been approved for examination as authorized by Missouri law.

(3) Testing. Applicants for licensure by examination shall successfully pass both the NAPLEX and the MPJE. To successfully pass, a minimum score of seventy-five (75) is required for each of the required examinations. Upon approval by the board and successful completion of the NAPLEX and MPJE, the board shall issue a pharmacist license to the applicant.

(4) Retesting. If an applicant fails to achieve a score of seventy-five (75) on both the NAPLEX and the MPJE, the candidate shall retake and pass the failed examination(s) before a license can be issued. Any applicant who fails to achieve a passing score on either of the examinations shall be required to file an application for reexamination with the board and pay the examination application fee each time. All examinations are scored independently and may be retaken independently.

(A) The board shall review and approve any applicant that fails the NAPLEX or MPJE two (2) consecutive times prior to the applicant being declared eligible to retest. A candidate shall not be declared eligible to retest under this subsection until approved by the board. In lieu of disapproval, the board may establish a date after which the candidate shall be eligible to retest or may establish additional training or study requirements to be completed before authorization to retest is granted.

(B) Application for reexamination shall be made on a form provided by the board. Fees for reexamination shall be non-refundable.


20 CSR 2220-7.040 Foreign Graduates

PURPOSE: This rule establishes licensure requirements for pharmacist applicants who are graduates from a pharmacy school/college not located in the United States or a United States territory.

(1) Definitions.

(A) Foreign school/college—For purposes of this rule, a foreign school/college shall be defined as a school/college of pharmacy that is not located in a United States (U.S.) state/territory.

(B) Preliminary evaluation application—The Application for Preliminary Evaluation of Foreign Pharmacy School Graduate provided by the board for graduates of a foreign school/college.

(2) Applicability. The provisions of this rule are applicable to all graduates of a foreign school/college, including, graduates currently or previously licensed as a pharmacist by another U.S. state/territory. Graduates from a foreign school/college of pharmacy shall comply with the provisions of this rule prior to filing an examination application, an application for pharmacist licensure, or a reciprocity application.

(3) Prior to applying for pharmacist licensure/examination, graduates of a foreign school/college shall first obtain Foreign Pharmacy Graduate Equivalency Certification (FPGEC) from the National Association of Boards of Pharmacy Foundation Foreign Pharmacy Graduate Examination Committee. Potential applicants shall pay all fees and comply with all application/certification procedures required by the National Association of Boards of Pharmacy Foundation Foreign Pharmacy Graduate Examination Committee.

(4) After receiving FPGEC, applicants shall file an application for preliminary evaluation with the board. Applications shall be submitted on a form provided by the board and accompanied by the application fee. The preliminary evaluation application shall include:

(A) A copy of a certificate showing proof of name, date of birth, and place of birth by one (1) of the following methods:

1. Birth certificate;
2. Baptismal certificate; or
3. Notarized statement from an authorized governmental agency.
(B) Documentation of name change, if the name on the credentials supplied for evaluation purposes is different than the name appearing on the application;

(C) Proof of fingerprinting as required by 20 CSR 2220-7.090;

(D) A copy of the applicant’s FPGE certificate;

(E) Proof of U.S. citizenship or, if the applicant is not a U.S. citizen, a copy of current visa, along with a copy of a U.S. employment authorization document such as an Alien Registration Receipt Card, Form I-551 or Employment Authorization Card Form I-688-B, or any other document approved or issued by the U.S. government permitting employment in the U.S.; and

(F) Documentation as required by the board showing proof of one thousand five hundred (1,500) hours of pharmacy practice experience related to the practice of pharmacy or proof that the applicant has maintained an active pharmacist license in another U.S. state/territory for a period of not less than one (1) year. To be eligible for licensure, the one thousand five hundred (1,500) hours of pharmacy practice experience must have been earned in a U.S. state/territory after the date the applicant obtained FPGE certification. Applicants who have not yet completed the one thousand five hundred- (1,500-) hour experience requirement shall may apply for licensure as an intern pharmacist and shall complete the required one thousand five hundred (1,500) hours before approval of the applicant’s preliminary evaluation application is approved.

(5) Reciprocity/License Transfer. After the preliminary evaluation application has been approved by the board, graduates of a foreign school/college that are currently licensed in another U.S. state/territory shall be governed by, and shall apply for licensure by license transfer/reciprocity pursuant to, 20 CSR 2220-7.050.

(6) Test Scheduling for Foreign Graduates Applying for Licensure by Examination. When an application has been completed, the board shall will notify an applicant if he/she is eligible for the North American Pharmacist Licensure Examination (NAPLEX) and/or Multistate Pharmacy Jurisprudence Examination (MPJE) examinations. The applicant shall schedule test dates for both the NAPLEX and MPJE with the National Association of Boards of Pharmacy (NABP). The applicant shall satisfy all testing and scheduling requirements established by NABP and shall complete any necessary application(s) and payment of fee(s) for scheduling/taking the examination(s).

(A) To avoid forfeiture of eligibility, the applicant must take the examination(s) within three hundred sixty-five (365) days after having been determined eligible for examination by the board. If the applicant does not take the examination within three hundred sixty-five (365) days, the applicant shall be required to reapply to the board for examination/licensure and again pay the examination application fee.

(B) A determination by the board that an applicant is eligible for examination does not guarantee that the applicant will be issued a Missouri pharmacist license. The board reserves the right to deny an applicant for licensure that has been approved to take the required examinations as authorized by Missouri law.

(7) Testing. Applicants for licensure by examination shall successfully pass both the NAPLEX and the MPJE examinations. A minimum score of seventy-five (75) is required for each of the required examinations. Upon approval by the board and successful completion of the NAPLEX and MPJE, the board may issue a pharmacist license to the applicant.
(8) Retesting. If an applicant fails to achieve a score of seventy-five (75) on both the NAPLEX and MPJE, the candidate shall retake and pass the failed examination(s) before a license can be issued. Any applicant who fails to achieve a passing score on either of the examinations shall file an application for reexamination with the board and pay the examination application fee each time. All examinations are scored independently and may be retaken independently.

(A) The board shall review and approve any applicant that fails the NAPLEX or MPJE two (2) consecutive times prior to the applicant being declared eligible to retest. A candidate shall will not be declared eligible to retest under this subsection until approved by the board. In lieu of disapproval, the board may establish a date after which the candidate shall be eligible to retest or may establish additional training or study requirements to be completed before authorization to retest is granted.

(B) Application for reexamination shall be made on a form provided by the board. Fees for reexamination shall be non-refundable.

(9) Upon approval by the board and successful completion of the NAPLEX and MPJE, the board shall issue a pharmacist license to the applicant.

(10) A preliminary evaluation application shall be deemed invalid if the applicant fails to submit all information required to complete the application within six (6) months after the application is received by the board. However, a preliminary evaluation application shall not be deemed invalid if the applicant has applied for licensure as a Missouri intern pharmacist to complete the required pharmacy practice experience and has completed all other preliminary application requirements, provided the application shall be deemed void if the applicant fails to complete the required pharmacy practice experience within two (2) years from the date the preliminary evaluation application was initially received by the board.


PURPOSE: This rule establishes requirements for applicants for pharmacist licensure by license transfer/reciprocity.

(1) The provisions of this rule shall be applicable to applicants for pharmacist licensure that are currently registered or licensed as a pharmacist in another United States (U.S.) state/territory who desire to be licensed by reciprocity or license transfer.

(2) Foreign Graduates. Graduates of a school/college of pharmacy not located in a U.S. state/territory shall first comply with 20 CSR 2220-7.040.

(3) Individuals seeking licensure by license transfer/reciprocity shall first file a preliminary application for license transfer with the National Association of Boards of Pharmacy (NABP). Potential applicants shall pay all NABP required fees and comply with all applicable NABP requirements.

   (A) After NABP’s review of the preliminary application, NABP will forward the official application for license transfer/reciprocity to the applicant which shall be completed and filed with the board along with the application fee. The official application shall be notarized and shall be accompanied by proof of fingerprinting as required by 20 CSR 2220-7.090.

   (B) The NABP official application shall be submitted to the board no more than three (3) months from the issue date of the official application as designated by NABP. If the official application is not submitted to the board within the required three (3) months, the applicant shall be required to apply to NABP for reevaluation of their application and for an extension of the NABP issuance date. Applicants shall complete all reevaluation/extension requirements and pay all applicable fees required by NABP.

(4) Applicants for license transfer/reciprocity shall pass the Multistate Pharmacy Jurisprudence Examination (MPJE) for Missouri. Upon review of the official application, the board shall notify NABP if the applicant is eligible to take the MPJE. A minimum score of seventy-five (75) is required for each of the required examinations. To be eligible for examination, the applicant shall—

   (A) Be currently registered or licensed as a pharmacist in another U.S. state/territory;

   (B) Have been licensed as a pharmacist by examination in another U.S. state/territory;
(C) Have completed one thousand five hundred (1,500) hours of pharmacy practice experience related to the practice of pharmacy as determined by the board or **shall** have maintained an active pharmacist license for a period of not less than one (1) year in the state from which they are transferring that is not under disciplinary action; and

(D) Submit a copy of the applicant’s Foreign Pharmacy Graduate Equivalency Committee Certification (FPGEC) certificate if the applicant is a graduate of a school/college of pharmacy not located in the United States.

(5) Test Scheduling. When an application has been completed, the board **shall** notify the applicant if he/she is eligible for the MPJE examination. The applicant shall schedule a testing date for the MPJE. The applicant shall satisfy all testing and scheduling requirements established by NABP. The applicant shall be responsible for completing any necessary application(s) and payment of fee(s) for scheduling/taking the examination.

(A) To avoid forfeiture of eligibility, the applicant must take the examination within six (6) months after having been determined eligible by the board for examination. If the applicant does not take the examination within six (6) months, the applicant shall be required to reapply to the board for examination/licensure and again pay the reciprocity application fee.

(B) A determination by the board that an applicant is eligible for examination does not guarantee that the applicant will be issued a Missouri pharmacist license. The board reserves the right to deny an applicant for licensure that has been approved to take the MPJE, as authorized by Missouri law.

(6) Retesting. If an applicant fails to achieve a score of seventy-five (75) on the MPJE, the candidate shall retake and pass the examination before a license can be issued. Applicants who fail to achieve a passing score shall file an application for reexamination with the board and pay the examination application fee each time. All examinations are scored independently and may be retaken independently.

(A) The board shall review and approve any applicant that fails the MPJE two (2) consecutive times prior to the applicant being declared eligible to retest. A candidate **shall** not be declared eligible to retest under this subsection until approved by the board. In lieu of disapproval, the board may establish a date after which the candidate **shall be** eligible to retest or may establish additional training or study requirements to be completed before authorization to retest is granted.

(B) Applications for reexamination shall be submitted on a form provided by the board. Fees for reexamination **shall be** non-refundable.

(7) Upon approval by the board and successful completion of the MPJE, the board may issue a pharmacist license to the applicant. All required fees must be paid prior to approval of a license transfer.

20 CSR 2220-7.070 Temporary Pharmacist License (Post-Graduate Training)

PURPOSE: This rule establishes requirements for obtaining a temporary pharmacist license to practice pharmacy for pharmacists completing post-graduate training programs.

(1) Applicants for Post-Graduate Training. Pursuant to section 338.043, RSMo, a pharmacist licensed or registered in another state may apply for a temporary pharmacist license to complete a post-graduate pharmacy training program in the state of Missouri.

(2) Applicants for a temporary pharmacist license shall file an application on a form provided by the board with the application fee. The application will not be considered unless it is fully completed and properly attested. The application shall include:

(A) The name and signature of a Missouri-licensed pharmacist who will be supervising the applicant. The supervising pharmacist’s license shall be active in Missouri and shall not be under discipline with the board;

(B) The name and address of all locations where the applicant will be practicing and a description of the applicant’s proposed duties;

(C) A portrait photograph which measures two inches by two inches (2” × 2”); and

(D) A protocol which outlines the applicant’s duties. At a minimum, the protocol shall define and include:

1. The type of practice to be performed and a specific job description of professional duties and functions to be completed;
2. The identity of the supervising pharmacist which includes a statement attesting to the ability and understanding of responsibilities involved;
3. A complete listing of all affiliations to be utilized during the licensure period; and
4. A complete listing of all locations where professional services will occur.

(3) A Missouri-licensed pharmacist who agrees to supervise a temporary pharmacist licensee shall conduct general supervision during his/her tenure as supervisor. General supervision is defined as supervision required to ensure the temporary pharmacist licensee is practicing in compliance with Missouri law. In addition, the supervisor must be available for consultation with the licensee whenever necessary. The supervising pharmacist and the temporary pharmacist licensee shall timely submit reports to the board as may be required through protocol or as requested by the board in assessing outcomes or adherence to board requirements.

(A) No applicant for a temporary pharmacist license shall commence practicing until the temporary pharmacist license is issued.
(B) The board may terminate a temporary pharmacist license at its own discretion if, in the opinion of the board, any of the board requirements have not been adhered to. The licensee shall be notified in writing by mail when board action results in the termination of a temporary pharmacist license.

(C) A temporary pharmacist licensee shall only be authorized to practice pharmacy at the location(s) identified in the temporary pharmacist’s application for licensure. A temporary pharmacist shall notify the board if the temporary licensee changes his/her supervising pharmacist. The board shall approve a change in supervising pharmacist prior to the supervision commencing. A temporary pharmacist licensee shall not practice under the supervision of a pharmacist without approval of the board.

(D) A temporary pharmacist license issued pursuant to this rule automatically expires at the end of the applicant’s Missouri-based training program identified in the application and protocol. Temporary pharmacist licensees shall not practice pharmacy in this state beyond the expiration date of their temporary license.

(4) The temporary licensing program is not intended to replace or conflict with any requirements or provisions of Missouri law or the rules of the board regarding internships or pharmacy practice experience. Students enrolled in a school/college of pharmacy seeking to rotate through a licensed pharmacy or to gain pharmacy practice experience in Missouri shall not qualify for licensure under this section but may apply for an intern license as governed by the rules of the board.

(5) If a temporary pharmacist licensee desires to acquire a permanent license or desires to practice pharmacy outside the provisions of this rule, then the temporary licensee shall be required to complete all applicable Missouri pharmacist licensure requirements. If a permanent pharmacist application is denied by the board, the temporary pharmacist license shall be considered invalid after notification is sent to the applicant/licensee by certified mail.


Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 7—Licensing

SHALL = 44/25
MUST = 7/6

[37% Reduced]

20 CSR 2220-7.080 Pharmacist License Renewal and Continuing Pharmacy Education

PURPOSE: This rule establishes renewal and continuing education requirements for relicensure of pharmacists in Missouri.

(1) All pharmacist licensees shall apply to renew their Missouri pharmacist license on or before October 31 of every even-numbered year. Applicants shall file a renewal application on a form provided by the board and pay the renewal fee. The renewal application must be completed correctly and in its entirety in order for it to be processed and the license renewed. Any portion of the application that is Incomplete or inaccurate shall result in the rejection of the renewal application and require its renewals will be rejected and returned to the applicant for correction.

(A) No active pharmacist license will be renewed by the board unless the applicant has fulfilled the continuing education requirements as set forth in section 338.060, RSMo, and the provisions of this rule. At the time of renewal, a licensee shall truthfully attest he/she has completed the continuing education requirements required by this rule. The attestation shall be submitted with on the renewal application and shall truthfully affirm that the licensee has completed all continuing education requirements and that proof of continuing education completion has been maintained by the pharmacist as required by section (2) of this rule. The required continuing education must be completed by the date the renewal is signed or submitted to the board.

(B) A Missouri pharmacist license that has not been renewed by the board on or before October 31 of each even-numbered year shall be deemed expired. Upon expiration, the holder of an expired license shall be deemed no longer licensed and shall not be required to pay all delinquent fees. A delinquent fee shall not be required if the renewal application was postmarked or submitted via the board’s electronic renewal system on or before October 31 of each even-numbered year. Renewal applications received prior to October 31 that are returned to the applicant for correction will not be considered late and subject to the delinquent fee if the corrected application is returned to the board within thirty (30) days after receipt.

(C) Any person who fails to renew his/her pharmacist license within two (2) years of its expiration shall will be treated in the same manner as a person who has never been licensed and shall be required to file a new pharmacist license application with the board.
(2) Required Hours. As a condition of renewal, all active Missouri pharmacist licensees shall complete thirty (30) hours of continuing education during the two (2) year continuing education reporting period preceding renewal of the license. For purposes of this rule, the reporting period is the twenty-four- (24-) month period beginning on November 1 of even-numbered years and ending on October 31 of even-numbered years. Continuing education hours earned after October 31 of even-numbered years shall apply to the next continuing education period.

   (A) A pharmacist first licensed by the board within twelve (12) months immediately preceding the October 31 biennial renewal date shall be is exempt from the continuing pharmacy education requirements for that reporting period.

   (B) Hours obtained in excess of the thirty (30) hours required by this rule may not be carried forward to satisfy the requirements for the next reporting period.

(3) Continuing Education Course Approval.

   (A) Except as otherwise provided herein, continuing education shall only be granted for a post-graduate course that is related to the practice of pharmacy and that is—

   1. Approved by the Accreditation Council for Pharmaceutical Education (ACPE) for continuing education;

   2. Offered by a state, federal, or local governmental or regulatory agency and approved by the board; or

   3. Related to the practice of pharmacy, as approved by the board.

   (B) Continuing education courses may include institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, professional meetings, self-study courses, and any other methods approved by the board. The courses must be pharmacy related and shall comply with the other continuing education requirements of this rule.

   (C) Continuing pharmacy education programs approved by ACPE shall be accepted as approved continuing education courses for purposes of license renewal and are not required to be individually submitted to the board for prior approval.

   (D) The board shall not grant Continuing education credit will not be granted for any course that is taken before it is approved by the board or ACPE.

   (E) One (1) continuing education contact unit (CEU) will be the equivalent of ten (10) clock hours of participation in programs approved by the board.

(4) Non-ACPE Approved Programs. Programs that are not ACPE approved must be approved by the board prior to being taken as a continuing education course. To be eligible for approval, a program shall provide for evaluation methods or examinations to assure satisfactory completion by participants. Additionally, the person(s) who is to instruct or who is responsible for the delivery or content of the program shall be qualified in the subject matter by education or experience.

   (A) Continuing education approval requests shall be submitted to the board on forms provided by the board. The applicant shall provide and include detailed information relating to administration and organization of the course, teaching staff, educational content and development, methods of delivery, facilities, and evaluation.
(B) Continuing education program approval applications should be submitted at least thirty (30) days prior to the date of the proposed continuing education program, to ensure the program is approved for continuing education credit prior to the course being taken. Applications received less than thirty (30) days prior to the date of the program cannot be guaranteed to be approved prior to the date of the program. No application for approval of continuing education programs will be accepted if received less than ten (10) business days from the date such program is to be offered for continuing education purposes.

(C) Applications returned due to errors or for purposes of requesting more information shall not be considered to be received by the board until the requested corrections and/or information are made and received by the board.

(D) The executive director shall review applications for continuing education programs and may approve or deny such requests. Applicants shall be notified. Applicants will be notified after a decision to approve or deny a program has been made.

(5) Credit for Educational Training.

(A) Any pharmacist who leads, instructs, or lectures to groups of nurses, physicians, pharmacists, or others on pharmacy-related topics in organized continuing education or in-service programs shall may be granted continuing education credit for the time expended during actual presentation upon adequate documentation to the board. However, a pharmacist whose responsibility is the education of health professionals shall only be granted continuing education credit for time expended in leading, instructing, or lecturing to groups of physicians, pharmacists, nurses, or others on board-approved pharmacy-related topics in an organized continuing education or in-service program outside of his/her formal responsibilities.

(B) Approval shall be requested using the procedures in section (4) of this rule. Credit for the same presentation or program will only be granted once during a renewal period.

(6) Graduate Studies. Continuing education credit will be given for undergraduate or graduate studies taken as a post-graduate in any regionally accredited pharmacy, medical, or dental educational institution of higher learning. To be eligible for credit, the studies must be related to the practice of pharmacy. Credit for undergraduate/graduate studies authorized by this rule shall will be assessed as follows:

(A) 3 hours college credit = 15 CE hours
(B) 2 hours college credit = 10 CE hours
(C) 1 hour college credit = 5 CE hours

(7) Licensees may obtain four (4) hours (0.4 CEU) of continuing education by attending a complete open session of a board meeting at which disciplinary hearings are scheduled, subject to the following:

(A) The licensee must sign in with the executive director or designee of the board before the meeting day begins;

(B) Licensees cannot receive continuing education credit for attendance at a board meeting if required to appear before the board;
(C) The licensee must remain in continuous attendance during the open session meeting, provided attendance shall not be required for more than eight (8) hours of an open session meeting. Except as otherwise provided in this section, partial credit will not be given if the licensee is not in attendance for the entire open session meeting;

(D) The maximum continuing education hours allowable for board meeting attendance pursuant to this subsection shall be limited to eight (8) credit hours (0.8 CEU) per biennial pharmacist renewal period.

(8) No information or advertisements shall contain information that a continuing education program has been approved by the board unless the program is accredited by ACPE or notification has been received from the board that the program has been approved.

(9) Inactive Licenses. In lieu of submitting proof of continuing education, a pharmacist may apply for an inactive license at the time of license renewal. To be deemed inactive, the pharmacist shall file a renewal application with the board with the applicable fee and request inactive status on the renewal application. An inactive license shall then be issued and may be renewed at subsequent renewal periods. While the inactive license is in effect, the pharmacist shall not practice pharmacy.

(A) The renewal fee will be the same for active and inactive licenses.

(B) Before an inactive license can be returned to active status, the licensee shall submit proper evidence that he/she has obtained at least fifteen (15) continuing education hours for each year that his/her license was inactive. The licensee may obtain the required continuing education hours during any time period while the license is on inactive status, as long as the hours are obtained prior to applying for return to active status.

(10) Any licensee who has an expired pharmacist license and seeks to renew the license pursuant to section 338.060.2, RSMo, shall present proper evidence that he/she has obtained the required number of continuing education hours during the period that his/her license was expired.

(11) A pharmacist shall maintain proof of completion of continuing education credits for a minimum of four (4) years after the continuing education has been completed. Licensees shall maintain a completed certification from ACPE or the approved continuing education provider indicating the course name and date of the program, the name of the participant, the date credit was earned, and, if applicable, the ACPE course number.

(12) The board may audit a licensee to assess the authenticity and validity of continuing education hours submitted for relicensure. Failure to provide proof of completion of the required continuing education credits when requested to do so by the board shall be considered a violation. In accordance with section 338.060, RSMo, any licensee that has not completed and retained the required evidence of all required continuing education shall pay any delinquent fees as prescribed by the board and may be subject to disciplinary action pursuant to section 338.055, RSMo. The board may also audit past renewal periods and/or require that proof of continuing education credits be submitted with the licensee’s renewal application.

#A10. Board Member Meetings Report

- Nuclear Sub-Committee
- DMH/NPA Naloxone Training
#A11. General Administration Report

- Staff/Office Update
- Financial Report
- 2018 Renewal Fee Decrease
- Rule Update
- Patient Safety Conference Survey
- Springfield Board Compliance Conference Survey
- NABP Annual Meeting (May 5-8 2018 – Denver, Colorado)
Missouri Board of Pharmacy 2017 Pharmacy Patient Safety Conference

Survey Results

There are 30 respondents to the survey.

How would you rate the value of this event
(1 very low, 5 very high)

<table>
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<th>Count</th>
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<tr>
<td>4 - high</td>
<td>12</td>
</tr>
<tr>
<td>3 - average</td>
<td>0</td>
</tr>
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<tr>
<td>1 - very low</td>
<td>0</td>
</tr>
</tbody>
</table>

30 of 30 answered this question.
How would you rate the knowledge you gained from the speakers (1 very low, 5 very high)

30 of 30 answered this question.

5 - very high 17
4 - high 12
3 - average 1
2 - low 0
1 - very low 0

How would you rate the venue (1 very low, 5 very high)

30 of 30 answered this question.

5 - very high 22
4 - high 6
3 - average 2
2 - low 0
1 - very low 0
How could we improve the events
1 It was peetty good as is
2 It was excellent. Great topics and speakers. Amazing that it was free to attend.
3 Longer day to increase c.e. credits.
4 was good
5 A speaker on "Patient safety culture". Which is the extent an organization's culture supports and promotes patient safety.
6 I thought this was well done - no suggestions for improvement on this
   Maybe share the slides via email as the presenters are speaking so we could see easily. I certainly understand not wanting to share them ahead of time, but as the presentation is going on would be helpful.
7 I thought it was great.
8 More frequent
9 Ok
10 not sure
11 I think it was as good as you could hope to get
12 Good as it is
13 None
15 I can't think of any. The venue, the food, the speakers, and etc were all very good.
16 The only comment was that it seemed there were several speakers overlapping their content. Would have liked to see a different topic or two added in.
17 Enjoyed meeting BOP and inspectors
18 More of a central location I'm coming from south of STL.
19 There is nothing I can think of. If the goal was to provide valueable information, you succeeded.
20 Everything was top notch
21 I loved it.
22 better sound system and temp control
23 I didn't receive info on this but my brother did, that's how I find out about it. Please be sure I am on the mailing list. Barry Wilson
24 sound and viewing bad.
25 speakers excellent especially good was the chief inspector
26 Not just review possible medication errors, but give detail on how to review and possibly prevent from happening in the future.
27 I think it was good. Maybe soft music just to break up the quietness:
28 Handout listing all the website addresses mentioned by the speakers
29 Overall thought the event was very well organized and the speakers were very informative
30 x
What is the one thing you really liked about this event?

1. Access to board staff
2. College of Pharmacy speakers were excellent.
4. Time, place, subject matter
5. Current information and resources presented
6. Moved quickly and stayed on task
7. I especially enjoyed listening to Dr. Glenski.
8. The overall quality of the content of the discussion.
9. Variety of speakers
10. Lunch
11. It was well balanced and offered enough breaks so it wasn't overwhelming
12. I thought the speakers were all very engaging, and their material was very relevant
13. Relevance to my practice
14. Hearing some new speakers, who knew the subject matter.
15. Having the time to meet with inspectors and Board members in a very relaxed setting.
16. The overall topic was exceptional.
17. Last presentation
18. Practical information provided
19. Great content, camaraderie, mixture of old and new pharmacists
20. How relaxed the event was to listen to
21. Topic and variety of speakers
22. Hearing Tom and Steve talks
23. The availability of the speakers, inspectors & Board members to speak to & ask questions of them.
24. Food was also good as well as the moderator
25. The location was great.
26. I liked the way that it was informative, yet kept moving. I also appreciated the catered food!
27. The space was sufficient. Was not cramped. Easy location. Speakers were not too long.
28. The knowledge gained
29. Speakers were excellent. Liked the fact that there wasn't a big long drawn out lunch. Thought all the food and snacks were great.
30. x
What is one suggestion you would make to improve this event?

1. More examples of patient safety best practices
2. The meeting room was freezing so turn up the heat.
3. Nothing great job, kept on track and good organization.
4. Handouts at event
5. Information on how to become an advocate for patient safety
6. More vibrant speaker/voice post lunch
7. I did not care for the first speaker. Her discussion was too low level.
8. Have ppts available ahead of time so we can print and bring
9. None
10. None
11. More organized check-in
12. Good as it is
13. Nothing, it was great.
14. None for now.
15. Possibly more local vendor booths.
16. My above comment
17. More active learning
18. None come to mind
19. Nothing
20. Closing speaker needs to be more brief.
21. Info on future planned regs
22. TVs or monitors on the walls in addition to the big screen up front and the speakers elevated so we could better see them.
23. See above.
24. I liked the CE. Could this be reported to the CPE monitor?
25. More interaction from participants. Maybe group activities for suggestions.
27. Was difficult to see the slideshow from the back --not sure how to fix that. If the speakers could have used a lavalier microphone it would have helped also.
28. 
29. x
Do you have any suggestions or further comments?

1. No
2. It would be great to have an option to receive ACPE credit for attending so the hours could apply to license renewal in additional states.
3. Outstanding conference.
4. 45 min max per speaker works best
   Patient safety is the responsibility of not only the pharmacist but the technician as well.
5. Reaching out to CPhT’s to attend this conference would promote patient safety on all levels.
6. Great event thank you for all the planning
7. None
8. Thanks to all involved
9. No
10. no
    I really thought that they did a wonderful job with this conference. It was a relaxed, while still professional atmosphere. The venue & foods were excellent. The program was about the right length. Long enough to make the trip worthwhile - but short enough to maintain interest
11. None
12. Very nice job preparing for this event...very successful day. Congratulations.
13. No
14. Not really except thanks for the opportunity and look forward to more in the future.
15. The meeting site was wonderful in every aspect. Keep the site if possible in the future.
16. put the ce in the online system
17. n/a
18. Thank you for a wonderful event. Appreciate the lunch, length of the event was perfect too. Not too short. Not too long.
19. Very good seminar
20. I was very impressed. I thank you for how much thought went into making such a nice day.
21. do this type of program more frequently
22. It would be nice to have one of these quarterly.
23. .
24. None.
25. ?
26. Thank you the venue was perfect. The snacks and water etc. was awesome. Your staff is very kind and attentive. Thank you it was not a boring conference. :
27. No
28. More informative events would be great
29. x
Missouri Board of Pharmacy Regulatory Update (Springfield)

Survey Results

There are 11 respondents to the survey.

How would you rate the value of this event
(1 very low, 5 very high)

11 of 11 answered this question.

<table>
<thead>
<tr>
<th>Rating</th>
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<tr>
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<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
How would you rate the knowledge you gained from the speakers
(1 very low, 5 very high)

11 of 11 answered this question.

5 - very high  4
4 - high       7
3 - average    0
2 - low        0
1 - very low   0

How would you rate the venue
(1 very low, 5 very high)

11 of 11 answered this question.

5 - very high  4
4 - high       3
3 - average    4
2 - low        0
1 - very low   0
How could we improve the events

1. It was a good event that stayed on topic, no improvement ideas that I can suggest.
2. N/A
3. I really enjoyed the live event compared to the webinars, although I know this can't be the norm.
4. Have proper CE accreditation. Better room temperature control
5. More comfortable location
6. No improvement
7. It was very good.
8. Continue to have localized events.
9. Yearly regional events coordinated with MPA regional events.
10. The event went very well... I can not think of any improvements
11. ?
What is the one thing you really liked about this event?

1. I liked the examples they talked about and appreciated the updates.
2. Straight answers
3. More live events throughout the year.
4. The variety of information presented
5. Hearing from chief inspector
6. Varied speakers
7. The openness of the Board of pharmacy members to help us stay in compliance.
8. The inspector's perspective around pharmacy inspections.
9. More in depth than our usual one hour updates.
10. The variety of speakers
11. Informative, based on not only regulations, but personal experience
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>none</td>
</tr>
<tr>
<td>2</td>
<td>N/A</td>
</tr>
<tr>
<td>3</td>
<td>nothing. Make it NABP approved so it can be entered into the monitor. Especially since you said in the presentation that pharmacists who do NOT have all of their CE in the monitor are at increased risk of BOP CE audit.</td>
</tr>
<tr>
<td>4</td>
<td>See question #1</td>
</tr>
<tr>
<td>5</td>
<td>no improvement</td>
</tr>
<tr>
<td>6</td>
<td>I cannot think of anything. Have the inspectors provide images of what good looks like when doing the patient safety portion of the presentation. We saw a lot of bad.</td>
</tr>
<tr>
<td>7</td>
<td>None</td>
</tr>
<tr>
<td>8</td>
<td>you did very well</td>
</tr>
<tr>
<td>9</td>
<td>I liked the food / drinks there</td>
</tr>
</tbody>
</table>
Do you have any suggestions or further comments?

1. Incorporate more hospital pharmacy information.
2. Well done.
3. None.
4. Thank you for providing this program in our area. It was nice not to travel.
5. See question #1
6. None
7. No
8. No.
9. None
10. Thanks for a great presentation.
11. ?
#A12. Inspection/Investigation Report

- Inspection/Investigation Updates
#A13. Hospital Advisory Committee Update
#A14. Implementation of SB 501/Rx Cares for Missouri Program
#A15. 20 CSR 2220-2.950 (Automated Filling Systems)

- Review of current requirements/Pharmacist verification standards
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. 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.

AUTHORITY: sections 338.250 and 338.280, RSMo 2000, and sections 338.140
30, 2014.
RSMo 1951, amended 2001, 2011; 338.250, RSMo 1951, amended 1990, 1998; and
#A17. *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 (should this be a different measurement such as CY 18). 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>Projected Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update Missouri statutes/Board rules to incorporate technician training and education requirements and modernize technician practice</td>
<td>As soon as possible</td>
</tr>
<tr>
<td>Review 100% of Board rules and prioritize revisions; Update as needed</td>
<td>* Currently ongoing</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>Projected Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consult with public relations professional to review Board’s communication activities and identify ways to enhance communication efforts to expand population reach and engagement</td>
<td>January 2018</td>
</tr>
<tr>
<td>Increase Board member/staff attendance at Missouri pharmacy related association meetings by 50%, including, the Missouri Pharmacy</td>
<td>June 30, 2018/December 31, 2018</td>
</tr>
</tbody>
</table>
Association and the Missouri Society of Health-System Pharmacists

<table>
<thead>
<tr>
<th>Performance Measure</th>
<th>Projected Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase attendance at fellow state medical Board meetings by 50% (e.g., the Board</td>
<td>June 30 2018/December 31, 2018</td>
</tr>
<tr>
<td>of Registration for the Healing Arts, the Board of Nursing, the Missouri Dental Board)</td>
<td></td>
</tr>
<tr>
<td>Reestablish the joint medical Board collaborative previously held with the Missouri Board of Registration for the Healing Arts, the Missouri Board of Nursing and the Missouri Dental Board</td>
<td>April 2018</td>
</tr>
<tr>
<td>Draft and circulate Board regulatory materials for inclusion in public relations</td>
<td>June 2018</td>
</tr>
<tr>
<td>materials/newsletters provided by other state medical Boards and Missouri pharmacy related associations</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>Projected Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pursue Inspector salary increases to increase retention and maintain institutional resources/expertise</td>
<td>2017-2018 legislative session</td>
</tr>
<tr>
<td>• Establish a succession plan for key Board positions, including, the Executive Director, Chief Inspector and Principal Assistant Position</td>
<td>June 30, 2018</td>
</tr>
<tr>
<td>• Survey Board staff to identify training and educational goals, needs and opportunities</td>
<td>January 2018</td>
</tr>
</tbody>
</table>

**GOAL # 4: Leverage technology and available resources to increase and enhance communication to licensees and relevant stakeholders.**

<table>
<thead>
<tr>
<th>Performance Measure</th>
<th>Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Consult with state information technology personnel to identify opportunities to increase and enhance Board’s technology use</td>
<td>April 2018</td>
</tr>
<tr>
<td>• Conduct strategic review of the Board’s website to identify ways to enhance user access</td>
<td>July 2018</td>
</tr>
<tr>
<td>Objective</td>
<td>Date</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Establish Board social media presence as authorized by state guidelines</td>
<td>July 2018</td>
</tr>
<tr>
<td>(e.g., Facebook or LinkedIn)</td>
<td></td>
</tr>
<tr>
<td>Increase e-alert enrollment by 35%</td>
<td>December 31, 2018</td>
</tr>
<tr>
<td>Increase website visits by 35%</td>
<td>December 31, 2018</td>
</tr>
</tbody>
</table>
#A18. Compounding For Office Use/Repackaging

- November 6, 2017 Correspondence to the Board
State Board of Pharmacy/State Board of Medicine

Re: Compounded and Repackaged Medications for Office-use

Dear Missouri Board of Pharmacy,

Our organizations represent physicians, pharmacists, other healthcare providers, surgical centers, and patient advocates treating and providing care to patients with an array of conditions requiring a broad spectrum of treatments and also pharmacists that provide physicians, hospitals, and other health care professionals with compounded medications for administration to and treatment of patients within these practice settings (often called “office-use”). As such, we have been closely monitoring the Food and Drug Administration’s (FDA) implementation of the Drug Quality and Security Act (“DQSA”, P.L. 113-54) and remain concerned about the impact of the Agency’s actions on patient access to compounded medications and the mass confusion amongst the States that has resulted.

Specifically, we remain deeply concerned about the FDA implementation of the DQSA in regard to both compounded and repackaged medications for office-use. Every day, compounding pharmacists serve patients in a variety of areas including: autism, oncology, dermatology and pediatrics. Compounding pharmacists also have served patients such as pre-term infants who require parenteral nutrition (PN). PN provides intravenous life-saving therapy for patients whose gastrointestinal (GI) tracts are not functioning or cannot be accessed or where nutritional needs cannot be met with oral or enteral diets. These are just a few examples of how compounding pharmacists are working with physicians to provide life-saving medications for patients.

Our organizations urge the members of your Board to delay consideration of any regulatory or policy decisions on the ability of practitioners to obtain and use office-use compounded preparations until such time as the Agency issues its guidance in a manner that is consistent with Congressional intent and that preserves patient access.

Congressional Intent and Actions

Maintaining access to potentially life-saving compounded medications is not only vital for patients, it is consistent with the legislative intent of the DQSA. While reinforcing Section 503A of the Food, Drug and Cosmetic Act (FDCA) through the passage of the DQSA, Congress came together in a bipartisan and bicameral fashion to make clear that pharmacists’ ability to provide compounded medications for a physician’s administration to or treatment of a patient within their practice should be left to the States.
During the passage of the DQSA, six bipartisan and bicameral statements were made on the record making clear to FDA of Congressional intent.\textsuperscript{287,288} These statements made clear that office-use compounding was to be left to state law and that the memorandum of understanding found within section 503A was not to include dispensing. Despite these clear statements, FDA has implemented the DQSA contradictory to these statements.

As with office-use, the DQSA did nothing to limit repackaging, and Congressional intent was that FDA would continue to allow the practice of repackaging of medications\textsuperscript{289} Actions by FDA to limit access to repackaged medications, either by requiring a patient-specific prescription in all cases or by not allowing pharmacists to engage in repackaging, would have significant consequences for patients who rely on these therapies.\textsuperscript{290}

Congress' multiple statements in the \textit{Congressional Record} show clear and overwhelming intent that compounded preparations for office-use remain available after the passage of the DQSA. These numerous statements as well as the strong urging from physician and pharmacy stakeholders, directed the agency to not limit office-use medication preparation by 503A compounders. In addition, when FDA considered changes to the Compliance Policy Guide (CPG) for human compounding several years ago, the draft CPG specifically provided for office-use compounding.\textsuperscript{291}

Despite these statements and its own draft guidance, FDA stated in final guidance that a compounding pharmacist or physician may not dispense compounded medications for office-use, but rather, must obtain or issue a prescription for an individually identified patient. As a result of these misleading statements by FDA, many States have taken recent action related to office-use compounding.

The actions by FDA to prohibit all office-use compounding has resulted in drastically reducing patient access to vital medications. There are numerous examples of medications that 503A traditional compounders currently supply for office-use in quantities that are too small or limited to justify preparation and distribution by a 503B outsourcing facility.\textsuperscript{292}

\textit{Congressional Appropriations Actions}

Following FDA's implementation actions, which are contradictory to Congressional intent, Congress has consistently and clearly continued to direct FDA as to Congressional intent. Congressional Appropriators


\textsuperscript{288} Representative Griffith (VA), Representative Burgess (TX), and Representative Green (TX), "Drug Quality and Security Act." \textit{Congressional Record} p.H5963. Available from: Thomas.gov; Accessed 11/24/2014.


\textsuperscript{290} Senator Isakson (GA), Senator Alexander (TN), Senator Harkin (IA), Senator Warner (VA), Senator Burr (NC), and Senator Boozman (AR), "Drug Quality and Security Act." \textit{Congressional Record} 159: 164 (November 18, 2013) p.S8071. Available from Thomas.gov; Accessed 11/24/2014.


\textsuperscript{292} See Appendix A for a compiled list of examples of medications supplied for office-use.
have acted to preserve patient access to these vital medications by including Appropriations Report language in the FY16, FY17, and FY18 (as passed out of Full Committee).

Specifically, during the Fiscal Year (FY) 2016 Omnibus Legislation, Congress approved House Report 114-2015. Within that, FDA was directed to issue guidance which specifically addresses how office-use compounding will be permitted. That guidance was required within 90 days of the final enactment of the report. This language stated -

The Committee is concerned that, since passage of the Drug Quality and Security Act (DQSA) of 2013, the FDA has interpreted provisions of Section 503A of the FDCA in a manner inconsistent with its legislative intent and with the agency's own previous positions. Specifically, the FDA has taken the position that under 503A, a pharmacist may not compound medications prior to receipt of a prescription and transfer the drugs to a requesting physician or other authorized agent of the prescriber for administration to his or her patients without a patient-specific prescription accompanying the medication. This practice, which is often referred to as 'office-use' compounding, is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that in 2012, prior to passage of the DQSA, FDA was working on a draft compliance policy guide for 503A of the FDCA that provided guidance on how 'office-use' compounding could be done consistent with the provisions of 503A. The Committee understands the intent of the DQSA was not to prohibit compounding pharmacists from operation under existing 503A exemptions; therefore, the Committee directs the FDA to issue a guidance document on how compounding pharmacists can continue to engage in 'office-use' compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A within 90 days after the enactment of this Act. (emphasis added). 293

When FDA ignored the FY 2016 Appropriations language, Congress again instructed FDA that the Agency does not have the authority to prohibit office-use compounding. During the FY 2017 Omnibus legislation, Congress included language stating

The Committee recommendation maintains fiscal year 2016 funding levels for the medical countermeasures initiative as well as recent funding increases for antimicrobial resistance, counterfeit drugs, food safety, foreign drug inspections, import safety, and pharmacy compounding. The Committee believes patient access to the right drug at the right time is of utmost importance. In instances where a commercially manufactured drug is not appropriate for a patient for a specific reason, a compounded drug may be the difference between life and death. Since passage of the Drug Quality and Security Act (DQSA) of 2013, the Committee has had concerns that the FDA interpreted provisions of Section 503A of the FDCA in a manner that might jeopardize the availability of compounded medications for "office use". The practice of "office use" occurs when a compounder will compound a batch of drugs in anticipation of receiving patient-specific prescriptions at a later time. It may also be the case of a doctor in his or her office maintaining compounded drugs on site because it is unsafe or impractical to issue a traditional prescription. This practice is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that on April 15, 2016, FDA released a new Draft Guidance on the issue of "office-use" compounding. The Committee directs the FDA to issue a Final Guidance


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that provides for “office-use” compounding of drugs, in appropriate circumstances as well as including drugs compounded in anticipation of a prescription for an identified individual patient. Such “anticipatory” compounded drugs must be based on the history of previous valid compound prescription orders, and on an established history between the prescriber and the patient and the compounder. (p 68-69).²⁹⁴

When FDA ignored both the FY 2016 and FY 2017 appropriations language, Congress included even stronger language within FY 2018 appropriations legislation and made clear that FDA does not have the authority to prohibit office-use and that office-use compounding is to remain a state regulated activity. In the FY 2018 Appropriations legislation as passed out of the Appropriations Full Committee, Congress states

The Committee continues to believe that patient access to the right drug at the right time is of utmost importance. In instances where a commercially manufactured drug is not appropriate for a patient for a specific reason, a compounded drug may be the difference between life and death. Since passage of the Drug Quality and Security Act (DQSA) of 2013, the Committee has had concerns that the FDA interpreted provisions of Section 503A of the FDCA in a manner that might jeopardize the availability of compounded medications for “office use”. The practice of “office use” occurs when a compounding pharmacy will compound a batch of drugs in anticipation of receiving patient-specific prescriptions at a later time. It may also be the case of a doctor in his or her office maintaining compounded drugs on site because it is unsafe or impractical to issue a traditional prescription. This practice is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee directed the FDA to issue a Final Guidance that provides for “office-use” compounding of drugs, in appropriate circumstances as well as including drugs compounded in anticipation of a prescription for an identified individual patient. Such “anticipatory” compounded drugs is based on the history of previous valid compound prescription orders, and on an established history between prescriber, patient and compounder. Despite clear directives in previous reports accompanying FDA’s appropriations bills for the agency to finalize guidance that authorizes office-use compounding, in December of 2016, the FDA finalized a Guidance for Industry (GFI) entitled “Prescription Requirement Under Section 503A of the FDCA,” which expressly prohibits office-use compounding. The Committee directs the FDA to rescind this GFI and issue a proposed rule, subject to the notice and comment provisions in the Administrative Procedure Act. The proposed rule should be consistent with Congressional intent as stated in both Appropriations Reports and the DQSA, and that also allows for office-use compounding as authorized by state law. In the proposed rule, FDA should lay out the means by which office use is permissible while addressing such critical safety matters, such as maintaining controls on quantity and safety issues such as those related to office stock shelf life. Lastly, FDA’s clarification on the line between traditional compounding and outsourced compounding will support state regulators, outsourcing facilities, and traditional compounders in their efforts to ensure that patients have access to safe compounded drugs while reducing the risks associated with sterile drugs produced in bulk. (page 67).²⁹⁵


Footnote continued on next page
Congressional Legislation

Congress has been clear. In addition to the Appropriations Legislation, Congress has taken additional steps to make very clear to the FDA that the Agency does not possess the authority to prohibit office-use compounding. Representatives Morgan Griffith and Henry Cuellar introduced bipartisan legislation with 31 cosponsors that leaves office-use compounding to be regulated by the States. The legislation makes very clear that FDA was never granted the authority under the DQSA to prohibit office-use compounding.\textsuperscript{296} The DQSA Coalition, which is comprised of over 35 organizations representing patients, providers, pharmacists, and other practitioners, sent a support letter for HR 2871 where 39 states signed on in support of the legislation.\textsuperscript{297} FDA was never given authority to regulate office-use by Congress. This is a state regulated activity that was always intended to be left to the states.

Congressional Letters to FDA

Congress has also sent letters to FDA expressing Congressional intent and continues to instruct FDA to leave office-use compounding to the States. In June 20, 2016, Representatives Chris Stewart and Henry Cuellar led a bipartisan letter signed by over 60 Members of Congress. The Members of Congress stated the following:

It is unacceptable that the FDA would ignore the Congress and continue to take the position that Section 503A specifically prohibits office-use compounding, despite clear congressional intent to the contrary and despite previous FDA actions that directly contradict that position, including the recent statement by Health and Human Services Secretary Burwell that also directly conflicts with FDA's current position on "office-use".

Prior to the passage of the Drug Quality and Security Act (DQSA) of 2013, FDA circulated a draft Compliance Policy Guide (CPG) in 2012 to Congress that recognized office-use as legitimate and permissible and explained how compounding pharmacists can engage in office-use compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A of the FDCA. The DQSA did not change the statutory language in 503A that was the basis of that CPG. During the consideration of the DQSA, six Members of Congress, on a bipartisan, bicameral basis, made statements in the Congressional record to clarify that the intent of the legislation was to preserve patient access to medications compounded for office-use.

Congress sent an additional letter on May 23, 2017 that was led by Representatives Chris Stewart and Buddy Carter with 65 bipartisan signatures and stated,

Office-use compounding of medications is a common and often necessary medical practice that is authorized in some form by the vast majority of state pharmacy laws. Compounding for office-use done pursuant to state pharmacy laws does not make a pharmacy a drug manufacturer, and Congress never intended for the FDA to assert regulatory authority over the traditional practice of pharmacy, which has always been regulated at the state level.


The policies finalized in this GFI are contrary to the plain language of Section 503A as amended by the Drug Quality and Security Act (DQSA) and ignore clear, bipartisan, bicameral congressional intent expressed during passage of the bill. The FDA has unfortunately chosen to ignore broad and diverse stakeholder input, multiple congressional letters from both chambers, and clear directives in the House Report accompanying the FY2016 FDA appropriations legislation (House Report 114-205). More importantly, the FDA’s misinterpretation of the law and related enforcement actions against pharmacies are jeopardizing patients' access to critical compounded medications. For these reasons, we respectfully request that the FDA immediately rescind this GFI and issue a proposed rule, with notice and stakeholder input as required by the Administrative Procedure Act, that is consistent with the DQSA and that allows for office-use compounding by state-licensed pharmacies where authorized by state pharmacy laws.

Our organizations urge the members of your Board to delay consideration of any pending regulatory or policy decisions on the ability of practitioners to obtain and use office-use compounded preparations until such time as the Agency issues its guidance in a manner that is consistent with this new Congressional directive. Additionally, we urge you to review and potentially reconsider any recent decisions to prevent, eliminate or restrict office-use compounding within your State.

Sincerely,

Alaska Pharmacists Association
Alabama Pharmacy Association
Alliance for Natural Health USA
American Academy of Dermatology Association
American Association of Naturopathic Physicians
American Pharmacists Association
American Society for Dermatologic Surgery Association
American Society for Mohs Surgery
Arkansas Pharmacists Association
California Pharmacists Association
Colorado Pharmacists Society
Compounding Pharmacists of Texas
Connecticut Pharmacists Association
Florida Pharmacy Association
Georgia Pharmacy Association
Illinois Pharmacists Association
Indiana Pharmacists Association
Integrative Medicine Consortium
International Academy of Compounding Pharmacists
Massachusetts Pharmacists Association
Maryland Pharmacy Association
MEDISCA
Michigan Pharmacists Association
Minnesota Pharmacists Association
Missouri Pharmacy Association
National Community Pharmacists Association
North Carolina Association of Pharmacists
North Dakota Pharmacists Association
Nebraska Pharmacists Association
New Jersey Pharmacists Association
New Mexico Pharmacists Association
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oregon State Pharmacy Association
PCCA
Pennsylvania Pharmacists Association
Pharmacists Society of the State of New York
South Carolina Pharmacy Association
South Dakota Pharmacists Association
Tennessee Pharmacists Association
Texas Pharmacy Association
Utah Pharmacy Association
Virginia Pharmacists Association
Washington State Pharmacy Association
West Virginia Pharmacists Association
The following are some examples of the medications that 503A traditional compounders currently supply for office-use in quantities that are too small or limited to justify preparation and distribution by a 503B outsourcing facility:

- **Topical Phenol** used by podiatrists and primary care physicians to treat in-grown toenails.
- **Topical cantharidin** (one strength is 52.5 mg / ml [0.7%]) used by podiatrists, primary care physicians, and dermatologists for the treatment of warts.
- **Topical podophylline** used by podiatrists, primary care physicians, and OB/GYNs.
- **Topical Diphenylcyclopropenone** in many strengths compounded from raw material and acetone for use by dermatologists treating alopecia areata.
- **Topical Squaric acid** for use by dermatologists in treating alopecia areata.
- **Bleaching gels** of various formulas used by dentists in teeth whitening procedures.
- **Glycolic acid solutions** used by dermatologists in skin peel procedures.
- **Trichloroacetic acid solutions** used by dermatologists in skin peel procedures.
- **Lidocaine, Epinephrine, and Tetracaine (LET or LAT) gel/solution and derivatives** used by ERs and Primary Care Physicians as a local anesthetic used to decrease pain while suturing patients – especially pediatric patients.
- **Dextrose capsules #0, 00, 000, 1, 2, 3, and 4** for use by Social Work to teach pediatric patients how to swallow capsules.
- **Tamsulosin 0.2 mg capsules** (open up the 0.4 mg capsules, weigh total contents then weigh in half; pack into #4 capsules) used off-label for kidney stones in pediatric patients.
- **Various powder-filled capsules** - many formulations out in the industry with mixtures of 3-4 ingredients that may include ciprofloxacin, amphotericin, dexamethasone, clotrimazole, and lidocaine and others for use in Sheehy-House powder insufflators for insertion into the ear to treat refractory external ear infections.
- **Topical Sodium Nitrate solution** used in labs for diagnosis of cystic fibrosis via sweat testing.
- **Topical Pilocarpine Nitrate solution** used in labs for diagnosis of cystic fibrosis via sweat testing.
- **Hydroxyzine pamoate suspension** for use by pediatric dentists for mild sedation || Combination antibiotic eye drop used by ophthalmology surgery centers.
- **EDTA ophthalmic eye drops** for surgery
- **Bevacizumab** (Avastin) repack used by ophthalmology clinics for treatment of wet macular degeneration.
- **Alteplase 1 mg / ml syringes** when commercial vials are on backorder and shortage from manufacturers.
- **Oxymetazoline Nasal Spray + Lidocaine 4% injection** compounded 1:1 in an ISO 5 environment and packaged into sterile oral syringes for storage in automated dispensing cabinets for ENT to use with an automizer prior to exam in office.
- **Surgical Irrigations**
  - Bacitracin 50,000 units in 0.9% nacl 3000 ml (bag).
  - Bacitracin 50,000 units in 0.9% nacl 1000 ml (bag or bottle).
  - Bacitracin 25,000 units in 0.9% nacl 500 ml (bottle).
  - Levofloxacin in 0.9% nacl 500 ml (bottle).
  - Cefazolin in 0.9% nacl 500 ml (bottle).
  - Bacitracin, Gentamicin and Cefazolin in 0.9% nacl 500 ml or 1000 ml (bottle).
- **Organ Transplant Irrigations, Soaks and Baths** o Cardioplegia solutions (mixtures of lidocaine, electrolytes, mannitol, dextrose, etc.).
  - Epinephrine in 0.9% nacl (bottle).
- Crash/Emergency Cart drugs/ICU/Ambulance/Helicopter/Airplane o Sodium Bicarbonate used by Anesthesia/ER crash carts, a sterile drug that has been on chronic backorder and shortage from manufacturers.
  - Calcium Chloride used by Anesthesia/ER crash carts/dialysis centers – chronic backorder from manufacturers.
  - Calcium Gluconate used by icus/dialysis centers; chronic backorder from manufacturers.
  - Propofol repackaged into 10 and 20 ml syringes during shortages.
  - Dexmedetomidine straight from diluted commercial vial or compounded with 0.9% NS and concentrated vial, then packaged in syringes.
  - Heparin 500 units/ml (3 ml) compounded then packaged in syringes for dialysis.
  - Heparin 2,000 units/ml (3 ml) compounded then packaged in syringes for dialysis.
  - Heparin 1,000 units/ml (3 and 8 ml) packaged in syringes for dialysis.
  - Lidocaine 1% buffered with nabicarb (0.8 & 5 ml) packaged in syringes for IV starts and dialysis.
  - Lidocaine with nabicarb (0.2 ml) packaged in J-tip syringes for IV starts and shos in ER, surgery centers, inpatient and clinics.
  - Heparin 2 units/ml compounded from Heparin and 0.45% nacl commercial products (250, 500 and 1000 ml bags) for storage in automated dispensing cabinets within health systems and long term care facilities.
  - Epinephrine 0.01 mg/ml compounded from epinephrine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
  - Epinephrine 0.02 mg/ml compounded from epinephrine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
  - Nicardipine 0.5 mg/ml compounded from Nicardipine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
  - Nicardipine 0.5 mg/ml compounded from Nicardipine and 0.9% nacl commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
  - Dextrose 10% plus 14.6% nacl or 23.4% nacl to prepare D10 and nacl 0.2% (25 ml) bag due to commercial product on chronic mfg b/o (prepared from commercial products).
  - Dextrose 10% plus 14.6% nacl or 23.4% nacl plus heparin to equal 1 unit/ml to prepare D10 and nacl 0.2% and Heparin 1 unit/ml (250 ml) bag (prepared from commercial products) may be stored in automated dispensing cabinets.
  - Bupivacaine 0.25% + Epinephrine = 1:200,000 injection for use in surgery and surgery centers.
  - Epinephrine 1:100,000 injection prepared from epinephrine and 0.9% nacl commercial products for use in surgery and surgery centers.
  - Epinephrine 1:400,000 injection prepared from epinephrine and 0.9% nacl commercial products for use in surgery and surgery centers.
  - Lidocaine 0.25% with Epinephrine 1:400,00 units injection prepared from commercial products in a vial for use in surgery and surgery centers.
  - Lidocaine 1% with Epinephrine 1:10,000 units injection prepared from commercial products into a vial for use in surgery and surgery centers.
  - Ropivacaine 0.2% with Epinephrine 1:200,000 units injection prepared from commercial products into a vial for use in surgery and surgery centers.
- Milrinone 0.2 mg / ml compounded or premix commercial product repackaged into 20 and 50 ml syringes for storage in automated dispensing cabinets.
- Pentobarbital 50 mg / ml commercial product repackaged into 1 ml syringe for cath lab and anesthesia surgery centers.
- Dopamine 1.6 and 3.2 mg / ml compounded or premix commercial product repackaged into 20 and 50 ml syringes for each for storage in automated dispensing cabinets.
- Nitroglycerin 0.4 mg / ml commercial product repackaged into 20 and 50 ml syringes during commercial product manufacturing back order and shortages.
- Iopamidol (Isovue) 61% injection repackaged into 20 ml syringes during Manufacturing back order and shortages.
- Botulinium Toxin solution reconstituted commercial product and packaged in syringes for office use treatment of spasticity, diagnosis of gastrointestinal disorders and which Dermatologists and Plastic surgeons also use.
- Ceftriaxone mixed with lidocaine to 350 mg / ml, drawn up in 1.1, 1.4 and 2.2 ml volumes in an ISO 5 environment for storage in an automated dispensing cabinet refrigerator in ets and clinics.
#A19. NABP Telepharmacy Request for Comments

- NABP Letter to State Boards
On October 24-25, 2016, NABP convened the Task Force on the Regulation of Telepharmacy Practice. The task force was established in response to Resolution 112-5-16, which was approved by the NABP membership at the Association’s 112th Annual Meeting in May 2016.

During the meeting, members of the task force discussed how telepharmacy can help provide patients with health care that they may not otherwise receive or have difficulty accessing. The task force agreed that residents in urban settings may benefit just as much as those in rural settings from the convenience and accessibility provided by telepharmacy. The task force decided that “Telepharmacy Practice” should be defined as the practice of pharmacy by registered pharmacies and pharmacists located within United States jurisdictions through the use of telepharmacy technologies between a licensee and patients or their agents at distances that are located within US jurisdictions.

One of the recommendations of the task force was that NABP should collaborate with state boards of pharmacy regarding the regulation of the act of telepharmacy between pharmacies and medical clinics or other facilities not regulated by the board of pharmacy. The practice of telepharmacy between pharmacies and medical clinics or other facilities is growing at a fast pace. The task force recognized that the practice of telepharmacy between pharmacies and medical clinics is not adequately regulated. One example that was brought up during the meeting is when an oncology clinic hires pharmacy technicians to compound and mix chemotherapy agents under the supervision of a remote pharmacist via telepharmacy technologies. When such remote supervision occurs between a pharmacist and a technician that is practicing in a facility that is not under the board of pharmacy purview, there may be insufficient regulation and public protection in place.

NABP is seeking input and collaboration from our members to determine how best to regulate such circumstances.

cc: NABP Executive Committee
#A20. STLCoP and UMKC College of Pharmacy

- STLCOP Site Listing
- STLCOP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing
#A21. Applications for Intern Training Special Site/Non-Pharmacist Preceptor

- DST Pharmacy Solutions, Inc.
- CVS/Pharmacy Management
- Schnucks Corporate Offices/Specialty Pharmacy Division
- Genesis HealthCare System-Information Technology
#A22. Board Disciplinary Report (For Informational Purposes)
## Licensees Presently Under Disciplinary Order

<table>
<thead>
<tr>
<th>Lic Num/Licensee</th>
<th>DBA</th>
<th>Complaint</th>
<th>Action Taken</th>
<th>Action From/Through</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016008710/Airgas USA, LLC</td>
<td>Airgas USA, LLC</td>
<td>2016-001289</td>
<td>Probation</td>
<td>Probation 08/24/2017 08/23/2019</td>
</tr>
<tr>
<td>Probation for two (2) years. Acted as a Wholesale drug distributor without an active Missouri drug distributor license. Section 338.055.2 (5), (6), (10), (12), and (13), RSMo.</td>
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<td></td>
<td></td>
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<tr>
<td>2015029209/Qualgen LLC</td>
<td>Qualgen</td>
<td>2016-005757</td>
<td>Probation</td>
<td>Probation 09/07/2017 09/06/2022</td>
</tr>
<tr>
<td>Probation for five (5) years. Entered into an order with Oklahoma. Licensee was disciplined in Oklahoma for deficiencies in practices for producing and compounding sterile drug products, failure to perform adequate investigations into sterility failures and engaging in the manufacturing of drugs and selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs. Section 338.055.2 (8), and (15)</td>
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</tr>
</thead>
<tbody>
<tr>
<td>042267/Baker, Susan H</td>
<td></td>
<td>Probation for two (2) years. Pharmacist's license disciplined by the Colorado State Board of Pharmacy, tested positive for marijuana. Section 338.055.2(8), and (15) RSMo.</td>
<td>Probation</td>
<td>01/28/2017 01/27/2019</td>
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<tr>
<td>043330/Berger, Randall M</td>
<td></td>
<td>Suspension for three (3) years, followed by probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from employer and sold them to other individuals; pled guilty to one felony count of conspiring, combining, confederate and agreeing with other persons known and unknown, to distribute hydrocodone. Section 338.055.2(2), (5), (13), and (15), RSMo.</td>
<td>Suspension</td>
<td>02/25/2011 10/31/2012</td>
</tr>
<tr>
<td>0200207612/Borman, Shawn D</td>
<td></td>
<td>Probation for five (5) years. Found guilty, or entered a plea of guilty or nolo contendere to one count of Fraudulently Attempting to Obtain a Controlled Substance, Section 338.055.2(1), (2), (5), (6), (13), (15) and (17), RSMo.</td>
<td>Probation</td>
<td>04/27/2016 04/26/2021</td>
</tr>
<tr>
<td>2003026181/Broadbent, Carmen K</td>
<td></td>
<td>Probation for three (3) years. As pharmacist-in-charge, misappropriated controlled substances from employer and sold them to other individuals; pled guilty to one felony count of conspiring, combining, confederate and agreeing with other persons known and unknown, to distribute hydrocodone. Section 338.055.2(2), (5), (13), and (15), RSMo.</td>
<td>Probation</td>
<td>11/24/2015 11/23/2020</td>
</tr>
<tr>
<td>042806/Cipponeri, Gerald J</td>
<td></td>
<td>Probation for three (3) years. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>Probation</td>
<td>03/07/2015 03/06/2018</td>
</tr>
<tr>
<td>042037/Deardeuff, John C</td>
<td></td>
<td>Revoked, and cannot reapply for seven (7) years. pled guilty to a felony in the United States District Court, Eastern Division, Missouri, of violating Title 21, United States Code, Section 843(a)(3) of possession of a controlled substance by fraud or forgery. Section 338.067, RSMo.</td>
<td>Revoked</td>
<td>09/15/2017 09/14/2024</td>
</tr>
<tr>
<td>042911/Drake, Mary V</td>
<td></td>
<td>Probation for two (2) years. As staff pharmacist, misappropriated legend drugs from employer for personal use without a valid prescription, and dispensed legend drugs to family members without a valid prescription. Failed to record the dispensing records in the pharmacy’s record keeping system. Section 338.055.2 (5), (6), (13), and (15), RSMo.</td>
<td>Probation</td>
<td>06/30/2017 06/29/2019</td>
</tr>
<tr>
<td>042911/Drake, Mary V</td>
<td></td>
<td>Sixty (60) days suspension--credit given for suspension served under Illinois disciplinary order, followed by Probation for five (5) years. Disciplinary action in Illinois relating to diversion of controlled substances from employer for personal use. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>Probation</td>
<td>01/03/2015 01/02/2020</td>
</tr>
</tbody>
</table>
### Licensees Presently Under Disciplinary Order

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<tr>
<td>042911/Drake, Mary V</td>
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<td>Suspension</td>
<td>01/03/2015</td>
<td>01/03/2015</td>
</tr>
<tr>
<td>201018151/Floyd, Joseph Lyn</td>
<td></td>
<td>Revoked</td>
<td>02/26/2016</td>
<td>02/25/2023</td>
</tr>
<tr>
<td>2010026492/Gates, Allison C</td>
<td></td>
<td>Probation</td>
<td>07/09/2016</td>
<td>07/08/2021</td>
</tr>
<tr>
<td>042059/Greaves, Mark A, Sr</td>
<td></td>
<td>Probation</td>
<td>10/22/2016</td>
<td>10/22/2020</td>
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<tr>
<td>040023/Haase, Mark E</td>
<td></td>
<td>Voluntary Surrender</td>
<td>06/02/2017</td>
<td>06/01/2021</td>
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<tr>
<td>045232/Harris, Craig</td>
<td></td>
<td>Probation</td>
<td>01/22/2016</td>
<td>01/21/2019</td>
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<tr>
<td>043616/Hoehn, Patricia A</td>
<td></td>
<td>Probation</td>
<td>08/11/2016</td>
<td>08/10/2020</td>
</tr>
<tr>
<td>040431/Hollaway, Daniel J</td>
<td></td>
<td>Suspension</td>
<td>09/12/2012</td>
<td>09/11/2014</td>
</tr>
</tbody>
</table>

**Pharmacist**

- **042911/Drake, Mary V**
  - **60 days suspension**--credit given for suspension served under Illinois disciplinary order, followed by Probation for five (5) years. Disciplinary action in Illinois relating to diversion of controlled substances from employer for personal use. Section 338.055.2(5), (6), (13), and (15), RSMo.

- **2001018151/Floyd, Joseph Lyn**
  - Revoked, and cannot reapply for seven (7) years. Misappropriated controlled substances from employers, incorrectly dispensed controlled and non-controlled substances, dispensed improperly labeled prescriptions, and use of controlled substances to the extent it impaired his ability to function as a pharmacist. Section 338.055.2(1), (5), (13), (15) and (17), RSMo.

- **2010026492/Gates, Allison C**
  - Five (5) years probation. Admitted to being under the influence of alcohol while practicing. Section 338.055.2(2), (5), and, (13), RSMo.

- **2010026492/Gates, Allison C**
  - Voluntary surrender of license, and cannot reapply for five (5) years. Admitted to diversion of controlled substances from employer. Plead guilty to violating 21 U.S.C.843 (a)(3). Section 338.055.2 (5), (6), (13), (15), and (17) RSMo.

- **2010026492/Gates, Allison C**
  - Voluntary surrender of license, and cannot reapply for five (5) years. Admitted to diversion of controlled substances from employer. Section 338.055.2 (5), (6), (13), (15), and (17) RSMo.

- **2010026492/Gates, Allison C**
  - Voluntary surrender of license, and cannot reapply for five (5) years. Admitted to diversion of controlled substances from employer. Section 338.055.3 RSMo.

- **040023/Haase, Mark E**
  - Voluntary surrender of license, and cannot reapply for five (5) years. Admitted to diversion of controlled substances from employer. Section 338.055.2(5), (6), (13), and (15) RSMo.

- **045232/Harris, Craig**
  - Probation for three (3) years. As pharmacist-in-charge, no annual review/missing sections of sterile products policies/procedures; failure to conduct annual process validation of aseptic technique; compounding log missing information; failure to maintain refrigerator/freezer temperature logs; unsecured storage of controlled substances; pharmacy permit did not include sterile compounding classification; improper prepackaging; unlawful sharing of CSOS certificate; inaccurate inventory; failure to electronically record receipts of CSOS orders; unsanitary conditions; improper dispensing of controlled substances; and failure to correct Compliance Notice deficiencies. Section 338.055.2(5), (6), (13), and (15), RSMo.

- **043616/Hoehn, Patricia A**
  - Probation for five (5) years. Pleaded guilty to the Class D Felony of using "False Statements Relating to Health Care Matters" in the United States District Court, Eastern District of Missouri. Section 338.065.1, RSMo.

- **040431/Hollaway, Daniel J**
  - Suspension for two (2) years followed by Probation for five (5) years. As owner and pharmacist-in-charge, misappropriated controlled substances from pharmacy; dispensed controlled substances to himself without a prescription, without proper labeling and without directions. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.
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<tr>
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<tbody>
<tr>
<td>040431/Hollaway, Daniel J</td>
<td>2008-002040</td>
<td>Probation</td>
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<td>2010-007303</td>
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<td>2013-038703/Huning, Grant Martin</td>
<td>Voluntary Surrender</td>
<td>07/26/2016 07/25/2023</td>
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<td>2012013212/Jackson, Hillary A</td>
<td>2014-000525</td>
<td>Suspension</td>
<td>01/30/2015 12/08/2015</td>
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<td>2013-006818</td>
<td>Suspension</td>
<td>06/21/2016 06/20/2019</td>
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<td>2010-001357</td>
<td>Suspension</td>
<td>06/22/2011 06/21/2013</td>
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<td>045077/Jones, Michael T</td>
<td>2014-000525</td>
<td>Probation</td>
<td>12/08/2017 12/07/2022</td>
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<td>2013-006818</td>
<td>Probation</td>
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<tr>
<td>040031/Kessler, Timothy E</td>
<td>2010-001357</td>
<td>Probation</td>
<td>06/22/2013 06/21/2018</td>
</tr>
</tbody>
</table>

Suspension for two (2) years followed by Probation for five (5) years. As owner and pharmacist-in-charge, misappropriated controlled substances from pharmacy; dispensed controlled substances to himself without a prescription, without proper labeling and without directions. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Suspension for two (2) weeks followed by Probation for five (5) years. Purchased controlled substances without a valid prescription for personal consumption. Section 338.055.2(1), (13), (15), and (17), RSMo.

Suspension for two (2) weeks followed by Probation for five (5) years. Purchased controlled substances without a valid prescription for personal consumption. Section 338.055.2(1), (13), (15), and (17), RSMo.

Suspension for two (2) weeks followed by Probation for five (5) years. Purchased controlled substances without a valid prescription for personal consumption. Section 338.055.2(1), (13), (15), and (17), RSMo.

Suspension for two (2) weeks followed by Probation for five (5) years. Misappropriation of controlled substances from employer; adulterated drugs. Plead guilty to a Class C felony of tampering with consumer products. Section 338.055.2(1), (5), (6), (13), (15), and (17) RSMo.

Administrative Hearing Commission granted temporary authority to suspend for one (1) year due to misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, consumed controlled substance without a prescription while working as a pharmacist. Section 338.055.4 and .5, RSMo.

Suspension for two (2) years followed by Probation for five (5) years. Misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, worked while impaired. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Suspension for two (2) years followed by Probation for five (5) years. Misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, worked while impaired. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Suspension for three (3) years, followed by Probation for five (5) years. Plead guilty to a felony regarding making false statements to federal officials. Section 338.065, RSMo.

Suspension for three (3) years, followed by Probation for five (5) years. Plead guilty to a felony regarding making false statements to federal officials. Section 338.065, RSMo.

Suspension for two (2) years followed by Probation for five (5) years. Misappropriated controlled substances from employer for personal consumption, falsified inventory records to cover up his misappropriation. Section 338.055.2(1), (5), (13), (15) and (17), RSMo.

Suspension for two (2) years followed by Probation for five (5) years. Misappropriated controlled substances from employer for personal consumption, falsified inventory records to cover up his misappropriation. Section 338.055.2(1), (5), (13), (15) and (17), RSMo.
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<tbody>
<tr>
<td>043358/Kimbel, Craig M</td>
<td>2008-000979 Suspension for three (3) years, followed by Probation for five (5) years. Pled guilty to three felony counts of Fraudulently Attempting to Obtain A Controlled Substance.</td>
<td>04/26/2010 04/25/2013</td>
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<tr>
<td>043358/Kimbel, Craig M</td>
<td>2008-000979 Probation for three (3) years, followed by Probation for five (5) years. Pled guilty to three felony counts of Fraudulently Attempting to Obtain A Controlled Substance.</td>
<td>04/26/2013 04/26/2018</td>
<td></td>
</tr>
<tr>
<td>2006009848/Kolkmeyer, Cindy Kay</td>
<td>2016-006024 Probation for two (2) years. As pharmacist-in-charge, failed to provide adequate security for controlled substances, maintain a valid Combat Methamphetamine Act self-certification, failed to conduct an annual controlled substance inventory, to maintain required policies and procedures and proper drug transfer records, compounded commercially available products, failed to offer patient counseling, maintain immunization administration records. unsanitary conditions in the pharmacy. Pharmacy had multiple controlled substance prescription violations.</td>
<td>06/15/2017 06/14/2019</td>
<td></td>
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<tr>
<td>2005000313/Krieg, Shannon M</td>
<td>2014-003733 Probation for two (2) years. Dispensing errors, Section 338.055.2 (5) and (13) RSMo.</td>
<td>12/08/2016 03/22/2018</td>
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</tr>
<tr>
<td>2009025376/Law, Amanda L</td>
<td>2013-000992 Probation for five (5) years effective 5/1/2016. Ingested a controlled substance obtained from employer without a valid prescription; pled guilty to felony possession of a controlled, then withdrew guilty plea following completion of drug court.</td>
<td>05/01/2016 04/30/2021</td>
<td></td>
</tr>
<tr>
<td>2004031557/Lindsey, Mika Lynn</td>
<td>2014-005282 Probation for five (5) years. Found guilty, or entered a plea of guilty or nolo contendere to selling pseudoephedrine without proper certification.</td>
<td>05/23/2016 05/22/2021</td>
<td></td>
</tr>
<tr>
<td>2001018155/Lowe, Teresa Ann</td>
<td>2014-004084 Probation for two (2) years. Dispensing errors, Section 338.055.2 (5) and (13) RSMo.</td>
<td>05/17/2016 05/16/2018</td>
<td></td>
</tr>
<tr>
<td>2005000316/Markley, Shawn E</td>
<td>2015-000354 Probation for five (5) years. Stole controlled substances, including phentermine, benzphetamine, and amphetamines from the pharmacy and ingested those without a valid prescription.</td>
<td>10/14/2017 10/13/2022</td>
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</tr>
<tr>
<td>Lic Num/Licensee DBA</td>
<td>Complaint</td>
<td>Action Taken</td>
<td>Action From/Through</td>
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<tr>
<td>2005007845/Maxwell, Rhonda L</td>
<td>Probation for three (3) years. As Pharmacist-in-Charge, failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Verified and dispensed prescriptions for pseudoephedrine under the name of a doctor, not lawfully authorized by the doctor; 2 of which were written and filled for Maxwell. Failure to report pseudoephedrine sales to the Missouri electronic pseudoephedrine tracking system. Misbranding; and record keeping violations, improperly labeled prescriptions. Section 338.055.2(5), (6), (13), (15), and (17), RSMo.</td>
<td>Probation</td>
<td>08/11/2016 08/10/2019</td>
</tr>
<tr>
<td>028380/Middleton, Darryl K</td>
<td>Probation for three (3) years. As pharmacist-in-charge, created and filled a prescription without prescriber authorization for himself to be used for his pet, misbranding and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>Probation</td>
<td>01/06/2016 01/05/2019</td>
</tr>
<tr>
<td>042307/Mitchell, Brian</td>
<td>Revoked, cannot reapply for five (5) years. Pled guilty to felony knowingly and willfully executing a scheme to defraud a health care benefit program. Section 338.065, RSMo.</td>
<td>Revoked</td>
<td>11/11/2015 11/10/2020</td>
</tr>
<tr>
<td>028332/Morris, Lynn A</td>
<td>Probation for three (3) years. Allowed employees to obtain non-controlled medications by creating prescriptions under the name of a doctor without the doctor’s authorization or without being physically examined by the doctor; dispensed prescriptions without doctor authorization; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>Probation</td>
<td>04/17/2015 04/16/2018</td>
</tr>
<tr>
<td>029418/Nippes, Jeffrey K</td>
<td>Revoked, cannot reapply for seven (7) years. Impaired pharmacist; misappropriated controlled substances from employer for personal consumption; pled guilty to one count of theft/stealing. Section 338.055.2(1), (2), (5), (13), (15), and (17), RSMo.</td>
<td>Revoked</td>
<td>05/31/2013 05/31/2020</td>
</tr>
<tr>
<td>028056/Nuber, Frank J</td>
<td>Probation for one (1) year. As pharmacist-in-charge, allowed a pharmacy technician to work while her registration was suspended. Section 338.055.2 (5), (6), (10), and (13), RSMo.</td>
<td>Probation</td>
<td>12/01/2017 11/30/2018</td>
</tr>
<tr>
<td>028845/Nyberg, Dwight K, Jr</td>
<td>Probation for five (5) years. As pharmacist-in-charge, diversion of controlled substances for personal use without a valid, patient specific prescription. Section 338.055.2(5), (13), (15), and (17), RSMo.</td>
<td>Probation</td>
<td>01/22/2016 01/21/2021</td>
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<tr>
<td>2000148445/Ori, Lee Eric</td>
<td>VOLUNTARY SURRENDER OF LICENSE EFFECTIVE 1/21/16</td>
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</tr>
<tr>
<td>2013-006282</td>
<td>Three (3) years probation. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and record keeping violations. Section 338.055.2 (4), (5), (6), (13), and (15), RSMo.</td>
<td>Probation</td>
<td>07/26/2016 07/25/2019</td>
</tr>
<tr>
<td>042773/Palans, Andrew G</td>
<td>Probation for three (3) years. As Pharmacist-in-Charge, dispensed controlled substances without valid prescription or proper authorization from prescriber, dispensed controlled substances without a valid patient-practitioner relationship, failed to maintain accurate controlled substance/prescription records; pharmacists immunizing without complete protocol. Failure to comply with REMS requirements (prescriber not properly certified). Misbranding of a controlled substance due to failure to comply with REMS requirements. Section 338.055.2 (5) (6), and (13), RSMo.</td>
<td>Probation</td>
<td>08/12/2016 08/11/2019</td>
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<tr>
<td>Pharmacist</td>
<td>Lic Num/Licensee DBA</td>
<td>Complaint</td>
<td>Action Taken</td>
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<tr>
<td>2005011039/Panian, Erin Thomas</td>
<td>2013-006921, Probation</td>
<td>Three (3) years probation. As staff pharmacist, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and record keeping violations. Section 338.055.2 (5), (6), (13), and (15), RSMo.</td>
<td>12/22/2016 12/21/2019</td>
</tr>
<tr>
<td>2009011857/Radtke, Amanda A</td>
<td>2012-005409, Revoked</td>
<td>Revoked, cannot reapply for seven (7) years. Misappropriated controlled substances from employers; created, forged and dispensed prescriptions that were not authorized and were not dispensed to real patients and either removed them for her own possession or provided them to unknown individuals. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>02/26/2016 02/25/2023</td>
</tr>
<tr>
<td>029924/Richardson, Mary R</td>
<td>2013-004480, Revoked</td>
<td>Revoked and cannot reapply for seven (7) years. Violation of discipline regarding failure to comply with Kansas Committee on Impaired Pharmacy Practice program, failure to enroll/activate FirstLab account, failure to submit documentation for a chemical dependency evaluation/program and documentation of support group attendance, and failure to submit compliance reports to the Board. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.</td>
<td>02/28/2014 02/27/2021</td>
</tr>
<tr>
<td>2001028180/Ross, Clintin Z</td>
<td>2013-002254, Suspension</td>
<td>Suspension for one (1) year followed by Probation for five (5) years. Pled guilty to two felony counts of stealing a controlled substance, illegally removed controlled substances from employers. Section 338.055.2(5), (13), and (15), and Section 338.065, RSMo.</td>
<td>11/11/2015 11/10/2016</td>
</tr>
<tr>
<td>2011032868/Satterfield, Ronald D</td>
<td>2012-001910, Probation</td>
<td>Probation for five (5) years. Dispensed legend and controlled substance prescriptions to himself without valid prescriptions, early refills, and misbranding. Section 338.055.2(5), (13), (15), and (17), RSMo.</td>
<td>06/26/2013 06/25/2018</td>
</tr>
<tr>
<td>2000827487/Schrock, Julie Ann</td>
<td>2014-000066, Probation</td>
<td>Probation for five (5) years. Removed and dispensed controlled substances to herself from employer pharmacies without valid prescriptions; misbranding. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.</td>
<td>09/17/2015 08/16/2021</td>
</tr>
<tr>
<td>2002022650/Stark, Kristina L</td>
<td>2011-004395, Revoked</td>
<td>Revoked and cannot reapply for seven (7) years. Violation of discipline involving failure to return licenses to Board office, failure to submit 6-month compliance reports, failure to submit to urinalysis testing, failure to complete alcohol/drug treatment program requirements, and failure to obtain mental health evaluation. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.</td>
<td>03/02/2012 03/02/2019</td>
</tr>
<tr>
<td>2011032868/Thompson, Timothy Eugene</td>
<td>2014-005340, Revoked</td>
<td>Revoked and cannot reapply for seven (7) years. Violation of discipline, removed controlled substances from employer pharmacy without a valid prescription and for which he did not pay; did not provide employer copy of Settlement Agreement. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>03/07/2015 03/06/2022</td>
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</tbody>
</table>
### Licensees Presently Under Disciplinary Order

<table>
<thead>
<tr>
<th>Lic Num/Licensee</th>
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</tr>
</thead>
<tbody>
<tr>
<td>040885/Trivedi, Kamlesh A</td>
<td></td>
<td>Probation for five (5) years. Removed and consumed Tramadol and diclofenac from the pharmacy without a valid prescription. Section 338.055.2 (13) and (17), RSMo.</td>
<td>Probation</td>
<td>12/13/2017 12/12/2022</td>
</tr>
<tr>
<td>042316/Wagenknecht, Mark A</td>
<td></td>
<td>Suspension for two (2) years, followed by Probation for five (5) years. Violation of discipline. Chemically dependent, repeatedly failed to call into Board's urinalysis testing program, failed to provide urine samples when requested. Section 338.055.2(1), (5), (6), (13), and (15), RSMo.</td>
<td>Suspension</td>
<td>03/15/2011 03/14/2013</td>
</tr>
<tr>
<td>028605/Walker, Michael L</td>
<td></td>
<td>Voluntary Surrender of license, cannot reapply for seven (7) years. Second violation of discipline; failure to take, maintain adequate records, and provide proof to the Board of continuing education hours; and refused to pay delinquent CE fee.</td>
<td>Voluntary Surrender</td>
<td>07/08/2014 07/07/2021</td>
</tr>
<tr>
<td>2007011416/Weaver, Britni N</td>
<td></td>
<td>Probation for two (2) years. As staff pharmacist verified and dispensed prescriptions for pseudoephedrine under the name of a doctor, not lawfully authorized by the doctor. Failure to report pseudoephedrine sales to the Missouri electronic pseudoephedrine tracking system. Record keeping violations, improperly labeled prescriptions. Section 338.055.2(6), and (15) RSMo.</td>
<td>Probation</td>
<td>01/11/2017 01/10/2019</td>
</tr>
<tr>
<td>029907/Williams, James H, Jr</td>
<td></td>
<td>Probation for five (5) years. Disciplinary action in Kansas relating to diversion of controlled substances for personal use. Section 338.055.2 (1), (5), (13), (15) and (17), RSMo.</td>
<td>Probation</td>
<td>09/15/2016 09/14/2021</td>
</tr>
<tr>
<td>2005007715/Young-Guffey, Wendy S</td>
<td></td>
<td>Revoked and cannot reapply for seven (7) years. Violation of discipline involving expired license, failed to submit compliance reports, failed to comply with urinalysis testing program requirements, failed to take/pass jurisprudence exam, and failed to participate in alcohol/drug and mental health treatment programs. Section 338.055.2(1), (5), (6), (13), and (15), RSMo.</td>
<td>Revoked</td>
<td>10/13/2011 10/12/2018</td>
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<tr>
<td>Lic Num/Licensee DBA</td>
<td>DBA</td>
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<tr>
<td>004952/B P &amp; W Inc. Bruner's Pharmacy</td>
<td>2015-006722 Probation</td>
<td>12/14/2017 12/13/2020 Probation for three (3) years. Failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Section 338.055.2 (5),(6), (13), and (15), RSMo.</td>
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</tr>
<tr>
<td>2017028631/Caprock Compounding Pharmacy Inc Caprock Pharmacy</td>
<td>2016-004516 Probation</td>
<td>08/08/2017 08/07/2019 Pharmacy permit issued with probation for two (2) years. Shipping prescriptions into Missouri without an active Missouri pharmacy permit to do so. Section 338.055.1 and .2 (6) RSMo.</td>
<td></td>
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</tr>
<tr>
<td>2011012258/Care Pharmacy LLC Care Pharmacy LLC</td>
<td>2011-005302 Revoked</td>
<td>07/31/2015 07/30/2022 Revoked and cannot reapply for seven (7) years. Technician dispensing without a pharmacist on duty; dispensing controlled substances without a written prescription, and prescription error. Section 338.055.2(5) for incompetency, misconduct dishonesty and misrepresentation, (6), (13), and (15), RSMo.</td>
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</tr>
<tr>
<td>2011002754/Niemann Foods Inc County Market Pharmacy 375</td>
<td>2015-006030 Probation</td>
<td>05/13/2016 05/12/2018 Probation for two (2) years. Failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Pharmacists verified and dispensed prescriptions for pseudoephedrine under the name of a doctor, not lawfully authorized by the doctor. Employees created prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations, improperly labeled prescriptions. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
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<tr>
<td>2000158538/Dierbergs Markets Inc. Dierbergs Fenton Crossing Pharmacy</td>
<td>2015-007529 Probation</td>
<td>03/17/2017 03/16/2020 Probation for three (3) years. Pharmacist-in-Charge admitted that he diverted Fioricet and Oxycodone from the pharmacy. The pharmacy failed to provide effective controls and procedures to guard against the theft of controlled substances. Section 338.055.2 (5), (6), (13), and (15), RSMo.</td>
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<tr>
<td>2017026657/Downing Labs LLC Downing Labs</td>
<td>2014-004909 Probation</td>
<td>07/26/2017 07/25/2020 Pharmacy permit issued with probation for three years. Disciplined in other states for reasons that, if occurring in Missouri would constitute grounds for discipline or denial. Entered into a consent agreement for a permanent injunction with the FDA that Downing manufactured and distributed misbranded, adulterated sterile products in violation of federal drug laws. 338.055.2 (2), (5), (8), (13), and (15) RSMo</td>
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<tr>
<td>003475/Family Pharmacy Inc. Family Pharmacy</td>
<td>2014-007287 Probation</td>
<td>04/17/2015 04/16/2018 Probation for three (3) years. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
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<tr>
<td>2002026762/Lynn A. Morris, RPh. Family Pharmacy</td>
<td>2014-007289 Probation</td>
<td>04/17/2015 04/16/2018 Probation for three (3) years. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
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</tr>
<tr>
<td>2007028926/Family Pharmacy of Missouri LLC Family Pharmacy #5</td>
<td>2014-007288 Probation</td>
<td>04/17/2015 04/16/2018 Probation for three (3) years. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
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<tbody>
<tr>
<td>005915/Grove Professional Pharmacy Inc</td>
<td>Grove Pharmacy-Home Infusion Division</td>
<td>2013-006265</td>
<td>Probation</td>
<td>08/13/2016 08/12/2018</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Probation for two (2) years. Dispensed compounded products to practitioners for office use and for administration on persons other than or in addition to the prescribed patient. Dispensed drugs under prescriptions which did not contain the name of patients who were prescribed the drugs. Section 338.055.2 (6), (13), and (15), RSMo.</td>
<td></td>
</tr>
<tr>
<td>2013042651/Creative Compounds Inc</td>
<td>Harbor Compounding &amp; Home Health Pharmacy</td>
<td>2016-001095</td>
<td>Probation</td>
<td>11/18/2016 07/15/2020</td>
</tr>
<tr>
<td></td>
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<td>Probation until 07/15/2020. Entered into a Stipulated Settlement and Disciplinary Order with the California Board of Pharmacy for sterile and non-sterile compounding violations-failure to maintain records, failure to properly test sterile compounds, and failure to disclose required ownership information. Section 338.055.2 (5), (8), and (13), RSMo.</td>
<td></td>
</tr>
<tr>
<td>2015001161/John W Hollis Inc</td>
<td>John Hollis Pharmacy</td>
<td>2014-003644</td>
<td>Probation</td>
<td>01/14/2015 01/13/2018</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Restricted pharmacy permit issued on probation for three (3) years. Prior disciplinary action against president/owner's Tennessee pharmacist license due to alcohol and drug abuse. Section 338.055.2(8), RSMo.</td>
<td></td>
</tr>
<tr>
<td>2015001480/Lexi's Medicine, Inc.</td>
<td>Lexi's Medicine, Inc.</td>
<td>2014-007285</td>
<td>Probation</td>
<td>01/20/2015 01/19/2020</td>
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<tr>
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<td></td>
<td>Restricted pharmacy permit issued on probation for five (5) years. President/pharmacist-in-charge of prior permit pled guilty to knowingly selling pseudoephedrine at retail without possessing a valid self-certification from the Attorney General of the United States. Section 338.055.2(2) and (15), RSMo.</td>
<td></td>
</tr>
<tr>
<td>2008019033/Grand Medical Group, LLC</td>
<td>Medicine Shoppe Pharmacy</td>
<td>2013-006051</td>
<td>Probation</td>
<td>07/11/2015 07/10/2018</td>
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<td>Probation for three (3) years. Inspection violations including CII safe unlocked and CIII-Vs not dispersed through inventory, overfilled stock bottles, failure to timely complete controlled substance inventory, failure to provide patient counseling, labeling errors, failure to maintain distribution records, adulteration of drug products, failure to use gloves when handling tablets, and return to stock violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
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<tr>
<td></td>
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<td></td>
<td>Revoked, cannot reapply for seven (7) years. Pled guilty to felony knowingly and willfully executing a scheme to defraud a health care benefit program. Section 338.065, RSMo.</td>
<td></td>
</tr>
<tr>
<td>004254/Rider Drug Inc.</td>
<td>Rider Drug Inc.</td>
<td>2014-004022</td>
<td>Probation</td>
<td>01/22/2016 01/21/2019</td>
</tr>
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<td>Probation for three (3) years. No annual review/missing sections of sterile products policies/procedures; failure to conduct annual process validation of aseptic technique; compounding log missing information; failure to maintain refrigerator/freezer temperature logs; unsecured storage of controlled substances; permit did not include sterile compounding classification; improper packaging; unlawful sharing of CSOS certificate; inaccurate inventory; failure to electronically record receipts of CSOS orders; unsanitary conditions; improper labeling; improper dispensing of controlled substances; and failure to correct Compliance Notice deficiencies. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td></td>
</tr>
<tr>
<td>006018/Semo Drugs of Kennett, Inc.</td>
<td>Semo Drugs Of Kennett</td>
<td>2012-006772</td>
<td>Probation</td>
<td>01/06/2016 01/05/2019</td>
</tr>
<tr>
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<td></td>
<td>Probation for three (3) years. Technician theft of controlled substances, failure to maintain adequate security to deter theft of controlled substances. Section 338.055.2(6), RSMo.</td>
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</tbody>
</table>
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<thead>
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<tbody>
<tr>
<td>2011017243</td>
<td>Stroheckers Pharmacy</td>
<td>Probation for one (1) year. Entered into a consent order with Oregon. Pharmacy was disciplined in Oregon for compounding violations related to compounding of testosterone cypionate, specifically for dispensing misbranded sterile preparations, failure to properly compound sterile preparations, failure to follow pharmacy sterile compounding procedures and failure to properly notify patients of a recall. Pharmacy dispensed preparations of misbranded testosterone cypionate to nine (9) Missouri patients. Section 338.055.2 (5), (8), (13), and (15), RSMo.</td>
<td>05/09/2017</td>
<td>05/08/2018</td>
</tr>
<tr>
<td>2001019642</td>
<td>Rostie Enterprises, LLC</td>
<td>Revoked and cannot reapply for seven (7) years. Pharmacist-in-charge/owner participated in scheme whereby excessive, suspicious, unsigned controlled substance prescriptions faxed from an agent of out-of-state physicians were dispensed for cash. Section 338.055.2(5), (6), (13), and (15), as well as 4 CSR 220-2.010(1)(N).</td>
<td>01/07/2013</td>
<td>01/06/2020</td>
</tr>
<tr>
<td>2015039678</td>
<td>Village Fertility Pharmacy Inc.</td>
<td>Restricted permit issued on Probation for three (3) years. Shipped into Missouri prior to licensure and disciplinary action in other states. Section 338.055.2(4), (5), (6), and (8), RSMo.</td>
<td>11/05/2015</td>
<td>11/04/2018</td>
</tr>
<tr>
<td>006322</td>
<td>Walgreen Co. #04212</td>
<td>Probation for three (3) years. Failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Section 338.055.2 (6) and (15), RSMo.</td>
<td>08/22/2017</td>
<td>08/22/2020</td>
</tr>
<tr>
<td>000157695</td>
<td>Walgreens #05278</td>
<td>Probation for three (3) years. Loss of controlled substances due to technician diversion and failure to maintain security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.</td>
<td>03/17/2016</td>
<td>03/16/2019</td>
</tr>
<tr>
<td>200514836</td>
<td>Walgreens #09301</td>
<td>Probation for three (3) years. Loss of controlled substances due to technician diversion and failure to maintain security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.</td>
<td>05/17/2016</td>
<td>05/16/2019</td>
</tr>
<tr>
<td>003121</td>
<td>Wharf Pharmacy</td>
<td>Probation for three (3) years. Dispensed controlled substances without valid prescription or proper authorization from prescriber, dispensed controlled substances without a valid patient-practitioner relationship, failed to maintain accurate controlled substance/prescription records; pharmacists immunizing without complete protocol. Failure to comply with REMS requirements (prescriber not properly certified). Misbranding of a controlled substance due to failure to comply with REMS requirements. Inaccurate records, failure to keep records in a uniform fashion for at least 5 years. Section 338.055.2 (5) (6), and (13), RSMo.</td>
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<td>Probation until 10/23/2018. Entered into an Agreed Order with the Kentucky Board of Pharmacy for sterile and non-sterile compounding violations-failed potency tests, allowing technicians to work unsupervised and improper storage of compounded preparations. Controlled Substance prescriptions were dispensed utilizing a prescriber whose license and/or DEA registration was not current, allowing employees to work without proper licensure. Entered into an Executed Consent Order with the Oregon, Alabama, Colorado, and Texas Boards of Pharmacy based on the discipline imposed by the Kentucky Board of Pharmacy Section 338.055.2 (5), (8), and (13), RSMo.</td>
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These individuals are not eligible for employment as pharmacy technicians

*****Licensees should also check the Pharmacy Conditional Registration List and the HB 600 (tax suspension) list to verify authorization to work.******

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MISSOURI BOARD OF PHARMACY
Pharmacy Technician Conditional Registration List
These individuals are eligible for employment as pharmacy technicians under conditions printed on his/her registration
Revised 12/8/2017

*****Licensees should also check the Pharmacy Technician Employment Disqualification List and the HB 600 (tax suspension) list to verify authorization to work.******

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#A2  Board Licensing Statistics (For Informational Purposes)
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<tr>
<td>Pharmacists (active)</td>
<td>10,830</td>
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<tr>
<td>Pharmacists with Medication Therapy Services Classification</td>
<td>2,819</td>
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<tr>
<td>Pharmacists (inactive)</td>
<td>336</td>
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<tr>
<td>Temporary Pharmacists</td>
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<td>Interns</td>
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<td>Technicians</td>
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<td>Pharmacies – Instate (includes temporary phys)</td>
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<td>Pharmacies – Out of State</td>
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<td>Drug Distributors – Instate (includes temporary DDs)</td>
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<td>1,060 + 1 temporary drug distributors</td>
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<td>Drug Distributor Registrants</td>
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#A24A  Open Session Minutes
- July Minutes
- August Minutes
The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christina Lindsay at approximately 8:07 a.m. on July 12, 2017. Each item in the minutes is listed in the order discussed.

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

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

**Others Present**
Curtis Thompson, Legal Counsel

PRESIDENT CHRISTINA LINDSAY CALLED THE MEETING TO ORDER AT 8:07 A.M. AND ROLL CALL WAS TAKEN.

**MOTION TO CLOSE 8:07 A.M.**
At 8:07 a.m., Barbara Bilek made a motion, seconded by Christian Tadrus, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7),
(13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 8:07 A.M.

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on July 12, 2017, at approximately 8:49 A.M.

#A4. PUBLIC HEARING ON BOARD RULES PURSUANT TO EXECUTIVE ORDER 17-03

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

- Tomson George with Walgreens Co. asked the Board to revise 20 CSR 2220-2.080, 2.083 and 2.085 to accommodate electronic records in order to provide more efficient delivery of patient care.
- Joel Kurzman with the National Association of Chain Drug Stores (NACDS) asked the Board to amend 20 CSR 2220-6.040 to remove the additional continuing education requirements for pharmacists administering medication. Mr. Kurzman indicated pharmacists are already required to complete continuing education as part of their pharmacist license renewal requirements and noted administration techniques are not likely to significantly change over time.

#A5. 2018 Proposed Legislation: The following Board discussion was held:

- Pharmacy Technician Standards/Registration- The Board asked to amend the draft to define a registered technician as someone who supports or assists with the practice of pharmacy as defined by § 338.010. Bert McClary suggested modifying the advanced technician language to clarify the listed advanced technician duties are discretionary and not mandatory. Board consensus to revise the draft as discussed for approval at the next Board meeting.
- Licensing of Third Party Logistics Providers/Drug Outsourcers- Board consensus to proceed as drafted; Board members noted this proposal has been submitted for approval multiple times.
- Pharmacist Continuing Education- Board consensus to proceed as drafted.
- Charitable Pharmacy- Board members inquired about possible legal implications of the current language and asked if the legislative goal could be accomplished by rule. Board consensus to discuss further after consultation with general counsel.
- Civil Penalties- Board consensus to proceed as drafted.

#A6. 2020 Rule Review: The following Board discussion was held:

1 A full transcript of this agenda item is available at the Board office.
20 CSR 2220-2.400 (Compounding Standards of Practice): No public comments received; Douglas Lang and Christian Tadrus questioned if the Board should delay amending the rule in light of potential federal changes. Board consensus to hold for one (1) year and monitor federal changes.

20 CSR 2220-2.500 (Nuclear Pharmacy- Minimum Standards for Operation): Public attendee Samuel Leveritt expressed strong support for revising the rule; Christina Lindsay proposed establishing a nuclear sub-committee to review potential changes. Board consensus to establish a nuclear sub-committee as recommended; Public attendees Samuel Leveritt, Richard Vansant and Brent McHugh volunteered to participate. Douglas Lang volunteered to serve as the coordinating Board member. Mr. Lang recommended the sub-committee limit its review given USP’s anticipated nuclear pharmacy chapter.

20 CSR 2220-2.600 (Standards of Operation for a Class F: Renal Dialysis Pharmacy): No public comments received; Christian Tadrus asked if inspectors have observed compliance issues in this area. Tom Glenski indicated no significant compliance trends have been observed for in-state pharmacies. Board consensus not to revise at this time but to reconsider if compliance issues arise.

20 CSR 2220-2.675 (Standards of Operation/Licensure for Class-L Veterinary Pharmacies): No public comments received; Tom Glenski noted the rule was recently promulgated and reported no significant compliance issues have been reported/discovered. Board consensus not to revise at this time.

20 CSR 2220-6.100 (Pharmacy Standards for Dispensing Blood-Clotting Products): Douglas Lang noted the rule is based on national standards that haven’t changed; Tom Glenski indicated no significant compliance issues have been reported/discovered. Christian Tadrus asked if the rule could be narrowed; Kimberly Grinston reported the rule incorporates national standards required by statute. Board consensus not to revise the rule at this time.

#A7. Draft Rules Under Review: The Board reviewed the following rules:
- 20 CSR 2220-2.010 Pharmacy Standards of Operation
- 20 CSR 2220-2.012 Pharmacy Supervision
- 20 CSR 2220-2.090 Pharmacist-In-Charge

Suggested rule changes have been incorporated into Attachment A. A transcript of the full Board discussion is available at the Board’s offices. Board consensus to review the proposed changes at a future meeting prior to final approval.

#A9. Board Member Reports: The following reports were given:

- Douglas Lang reported he attended the pharmacy practice advancement meeting organized by Bert McClary and other MSHP representatives. Mr. Lang noted the group discussed potential legislation to expand pharmacy practice and legislation that would address pharmacist insurance reimbursement. Mr. Lang noted the meeting was productive and that organizers intended to consult other pharmacy stakeholders to
minimize legislative opposition. Mr. Lang reported he also attended the APhA Substance Abuse Institute in Salt Lake City, Utah, which provided valuable information on addiction and addiction treatment. Mr. Lang recommended other Board members attend, if possible.

- Pamela Marshall reported she attended the NABP meeting in Orlando which included several informative discussions on topics such as expanded technician roles, USP 800 and naloxone dispensing/administration. Ms. Marshall also reported attending the Missouri Health Advocacy Alliance meeting in June in her personal capacity and not as a Board member where she presented on PDMPs and the potential impact on Missouri pharmacists; Rep. Fredrick was in attendance. Presentations were also given on tort reform and healthcare access.

#A10. General Administration Report: Kimberly Grinston reported Joe Dino will be retiring at the end of July and thanked him for his commendable service to the Board; Mrs. Grinston also recognized Laura Henke for five (5) years of employment with the Board. Board members joined Mrs. Grinston in extending their congratulations and gratitude to Mr. Dino and Mr. Henke; President Lindsay presented recognition gifts on behalf of the Board.

#A7. Draft Rules Under Review (Cont’d) 1: Additional Board discussion was held on the following rules:

- 20 CSR 2220-2.025 Non-Resident Pharmacies: A motion was made by Pamela Marshall, seconded by Douglas Lang, to approve the rule for official filing. Motion passed 5:0:0:0 by roll call vote as follows:

  Anita Parran – yes  Christian Tadrus – yes

- 20 CSR 2220-2.950 Automated Filling Systems: No public comments; Board consensus to table pending additional review of an appropriate sample size.

- 20 CSR 2220-6.040 Administration by Medical Prescription Order: Board consensus to remove the continuing education requirement and to return the final draft for approval at a future Board meeting.

- 20 CSR 2220-6.050 Administration of Vaccines Per Protocol: Joel Kurzman (NACDS) indicated NACDS is recommending that pharmacists comply with ACIP guidelines when immunizing with minor modifications based on CDC recommendations; Mr. Kurzman further recommended lowering the minimum vaccination age to seven (7). Tom Glenski and Barbara Bilek indicated ACIP is part of the CDC which is referenced in the current rule draft. Board consensus to retain the continuing education requirement and to return the final rule amendment for approval at a future Board meeting.

#A15. Remote Technician Supervision/Remote Medication Verification: The following public comments were received:

Missouri Board of Pharmacy
Open Minutes
July 12-13, 2017
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• Adam Chessler with TelePharm spoke in favor of allowing remote technician supervision/verification and offered to assist with gathering language from other states.
• Greg Teale with St. Luke’s Hospital commented remote supervision/verification technology is currently used in hospital settings and noted the allowance would advance patient care if also allowed in care settings under the Board’s jurisdiction. Mr. Teale offered to demonstrate St. Luke’s system for the Board at a later date.
• Greg Guenther commented pharmacy practice is changing resulting in a greater demand for direct pharmacist patient care activities. Mr. Guenther suggested remote supervision/verification would allow an expanded patient care role and potentially decrease pharmacy operational costs. Mr. Guenther noted pharmacy operational costs are particularly significant given the continued decline in pharmacy reimbursement. Mr. Guenther suggested remote supervision/verification would also allow lower volume pharmacies to assist higher volume pharmacies which would increase patient services.
• Bert McClary supported the concept of remote supervision/verification and noted the allowance may help health systems expand services in rural areas. However, Mr. McClary cautioned the definition of remote supervision/verification should be carefully tailored to avoid unintended consequences.

Board discussion held; Christian Tadrus and Tom Glenski suggested the Board address remote supervision separately from remote verification and tech-check-tech. Barbara Bilek suggested the Board address the greatest need and the highest risk areas first. Public member Greg Teale commented there may be limited dispensing oversight in physician clinic areas and asked the Board consider remote supervision/verification as soon as possible to allow pharmacists to assist in non-pharmacy care settings in lieu of allied professionals who may not be as appropriately trained or qualified as a pharmacist. Further Board discussion held; Board consensus to have staff identify all rules that may be impacted or need to be amended if remote verification or remote supervision is allowed.

#A11. Inspection/Investigation Report: Tom Glenski reported on current inspection/investigation activities and provided the following updates:
• A new inspector will be starting August 4th in the territory left vacant after Joe Dino’s retirement.
• Sterile Compounding: Katie DeBold has created a revised sterile compounding guide and a sterile compounding handout for conducting remedial investigations. Inspectors visited a local pharmacy on July 11, 2017, where Mrs. DeBold provided hands-on training on inspecting/using isolators. Inspectors will be doing another sterile compounding training program at St. Louis College of Pharmacy at the end of July that will also be led by Mrs. DeBold. A sterile compounding webinar will be held on October 4th to provide compliance updates since the revised sterile compounding rule became effective a year ago.
• A full electronic inspection program has been initiated. Inspection reports will be e-mailed and will no longer be provided on CD.
#A12. Hospital Advisory Committee Update: Bert McClary reported the Committee met on May 5th and will be meeting again on July 17th. Mr. McClary provided the following updates:

- The Committee reviewed the proposed Class-J rule and Class-B guidance document and made preliminary suggestions for the Class-N Automated Dispensing Rule and an automated distribution rule. Mrs. Grinston noted staff is holding the Class-B guidance document in light of new legislation that is under review by the Missouri Dept. of Health and Senior Services.
- The Committee reviewed the Board’s medication therapy services rule and recommended the Board not revise the rule at this time given other legislative developments that may impact the rule.
- The Committee discussed the Board’s sterile compounding rule and did not have any formal comments at this time.
- Neil Schmidt resigned as the MSHP representative to focus on other family and professional goals; A new representative may be named shortly.
- Mr. McClary reported he has voluntarily resigned as chairman of the Committee and that a new chair will be selected. Mr. McClary will remain an active member of the Committee but noted rotating chairmanship will allow for a diversity of leadership and opinion.

#A13. Sterile Compounding Committee Update: Christian Tadrus reported the Committee met on June 23, 2017. Katie DeBold provided an update on reporting rates for positive environmental tests; The Committee discussed ways to address pharmacies suspending compounding in the event of a positive test. Discussion was also held on the impact of the beyond-use-date/in-use time rule requirements on nuclear pharmacy. Committee members expressed strong concerns about extended BUDs/in-use times particularly for multi-dose units that have stability beyond a 6-hour time frame. The Committee will continue discussions on if or how nuclear pharmacy should be accommodated.

#A14. Fiscal Year 2018-2019 Strategic Plan: Mrs. Grinston reported the Board previously asked staff to provide a template for a strategic plan to implement the recommendations from the Board’s 2016 strategic planning meeting. Board members suggested the following:

- Douglas Lang and Christina Lindsay asked if the Governor’s rule review goals could be used as a benchmark in Goal # 1.
- Christian Tadrus ask if the goal related to updating technician rules/statutes should be removed. Christina Lindsay suggested a performance measure could be to meet with relevant stakeholders regarding technician issues.
- Christian Tadrus and Anita Parran suggested a benchmark for goal # 2 could be producing information that could be published by the Missouri Pharmacy Association and other entities. Christina Lindsay recommended the Board focus on technology.
needs and suggested this may be an opportunity to ask for additional resources from the Governor’s office.

#A16. STLCOP and UMKC College of Pharmacy Site/Preceptor Lists: Tom Glenski recommended approval of both lists. A motion was made by Barbara Bilek, seconded by Douglas Lang, to approve the site/preceptor lists as presented. Motion passed 5:0:0:0 by roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang – yes
- Pamela Marshall – yes
- Anita Parran – yes
- Christian Tadrus – yes

Kimberly Grinston asked if the office could approve pharmacies and pharmacist preceptors if no discipline is listed. Board consensus to allow staff to approve pharmacies and pharmacist preceptors presented by STLCOP and UMKC if no discipline is identified; Disciplinary cases and special sites/non-pharmacist preceptors should still be approved by the Board.

#A17. Applications for Intern Training Special Site/Non-Pharmacist Preceptor: Tom Glenski noted a curriculum vitae for Pharmacie De La Tour has been included in the Board’s handouts. Mr. Glenski recommended approving all special sites/non-pharmacist preceptors listed but recommended the Board advise the Faith Community Health site that interns cannot be involved in the dispensing process since the site is not a pharmacy. Douglas Lang asked if the FDA site was previously approved; Mr. Glenski reported the site has been approved through 2019 but is adding a new non-pharmacist preceptor. A motion was made by Barbara Bilek, seconded by Christian Tadrus, to approve the special sites/non-pharmacist preceptors listed with a caution to Faith Community Health that interns cannot be involved in the dispensing process. Motion passed 5:0:0:0 by roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang – yes
- Pamela Marshall – yes
- Anita Parran – yes
- Christian Tadrus – yes

Douglas Lang indicated he would like to talk with the pharmacy schools about the level of use and the quality of experience at both the domestic and foreign special sites.

#A18. Election of Officers: Christina Lindsay nominated Christian Tadrus for President; Mr. Tadrus accepted the nomination. No other presidential nominations were made. A motion was made by Christina Lindsay, seconded by Pamela Marshall, to elect Christian Tadrus as president. Motion passed 4:0:1:0 by roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang – yes
- Pamela Marshall – yes
- Anita Parran – yes
- Christian Tadrus – abstain

A motion was made by Pamela Marshall, seconded by Barbara Bilek, to elect Douglas Lang as Vice-President. Motion passed 4:0:1:0 by roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang – abstain
- Pamela Marshall – yes
- Anita Parran – yes
- Christian Tadrus – yes

#A19. Legal Contract Approval: Board decision to hold pending further discussion in closed.

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

Anita Parran – yes  Christian Tadrus – yes

PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 4:01 P.M.

JULY 13, 2017

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on July 13, 2017, at approximately 10:23 A.M. All Board members/staff in attendance on July 12, 2017, were also in attendance on July 13, 2017.

#A19. Legal Contract Approval:
A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the legal contract for Newman, Comley and Ruth. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the legal contract for Curtis Thompson. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

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

DISCUSSION: The Board convened a disciplinary hearing at 10:30 a.m. Cotton Walker was present as counsel for the Board. Gerald Cipponeri was not present and was not represented by counsel. Mr. Walker provided an opening statement and presented exhibits. No closing statement was provided. The hearing adjourned at 10:37 a.m. A transcript of the hearing is available in the Board’s records.

MOTION TO CLOSE 10:38 A.M.
At 10:38 a.m., Barbara Bilek made a motion, seconded by Douglas Lang, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes
RECONVENE OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 12:57 a.m. on July 13, 2017.

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

#A21. Board Disciplinary Report

#A22. Board Licensing Statistics

MOTION TO ADJOURN 12:58 PM
At approximately 12:58 p.m., a motion was made by Barbara Bilek, seconded by Douglas Lang, to adjourn the July 2017 meeting. Motion passed 4:0:0:1 with roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

____________________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. The meeting was called to order by President Christian Tadrus at approximately 3:02 p.m. on August 9, 2017. Each item in the minutes is listed in the order discussed.

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

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

**Others Present**
Curtis Thompson, General Counsel

PRESIDENT CHRISTIAN TADRUS CALLED THE MEETING TO ORDER AT 3:02 P.M. AND ROLL CALL WAS TAKEN.

**ITEM #4 General Administration Report**

DISCUSSION: Executive Director Kimberly Grinston reported the Board’s proposed 2018 legislative items have been submitted for approval by the Department/Governor’s office; Updates will be provided once available.

**ITEM #5 Review of August Newsletter Draft**

DISCUSSION: The following Board discussion was held:
- Board members recommended including a list of prior Board officers in a future newsletter.
- Epinephrine Dispensing: Board members questioned the scope of training required for epinephrine users and questioned if pharmacists are required to verify that epinephrine purchasers have been appropriately trained. Kimberly Grinston
reported the statute does not require that pharmacists verify training. Christian Tadrus asked if pharmacists can provide the required training; Kimberly Grinston reported the statute says training must be from a national recognized entity or another entity/person approved by the Missouri Department of Health and Senior Services (DHSS). Board consensus to quote the statutory training language in the newsletter.

- **Naloxone:** Kimberly Grinston reported the proposed DHSS standing order has been included for Board review and highlighted that pharmacist notification to DHSS or the Board of intent to dispense naloxone is no longer required. Christian Tadrus suggested clarifying the difference between a protocol and standing order. Mr. Tadrus further recommended standardizing the measurement references in the standing order. Christian Tadrus asked if a drug distributor license was required if naloxone sales exceeded 5% of the pharmacy’s drug sales; Ms. Grinston indicated this may be a topic for legal counsel.

Additional Board discussion was held on labeling requirements for naloxone sales/dispensing; Kimberly Grinston reported the statue is generally silent on labeling. Board consensus to discuss further with legal counsel.

- **PDMP:** Board consensus to separately identify newsletter language written by DHSS. Douglas Lang asked if DHSS is considering emergency rules; Ms. Grinston reported DHSS is currently working on implementation plans and has not provided an implementation timeline.

- **Telepharmacy:** Christian Tadrus suggested the newsletter clarify that allowed tele-pharmacy activities may be performed remotely or inside a pharmacy. Ms. Grinston reported the Board of Healing Arts will be meeting with the Missouri Pharmacy Association to discuss pharmacy related telehealth issues.

**ITEM #6 Board Regulatory/Patient Safety Conference**

**DISCUSSION:** Pamela Marshall and Anita Parran provided updates on the upcoming Board regulatory/patient safety conference to be held in St. Louis, Missouri. Kimberly Grinston reported UMSL submitted the lowest bid and as a state entity would be a prime meeting site; Jennifer Luebbert will visit the conference center before finalizing a contract. Steve Calloway (Mo HealthNet) and Health Literacy of Missouri have agreed to present. Board discussion held; Board consensus to proceed with planning.

**ITEM #7 Applications for Intern Training Special Site/Non-Pharmacist Preceptor**

**DISCUSSION:** Jennifer Luebbert reported a Board member asked to discuss the Ewha Woman’s University and the Trinity College Dublin special sites included on a recent e-mail ballot. Barbara Bilek indicated it is unclear what activities interns will be participating in at these sites and expressed concerns that not all foreign pharmacies may be engaged in true pharmacy activities that would be appropriate for intern training. Board discussion held. Tom Glenski noted Trinity College is a renewal request and was
previously approved by the Board. Board consensus to approve the sites as designated on the e-mail ballot. Staff indicated UMKC and STLCoP will be discussing foreign sites at an upcoming Board meeting.

ITEM # 8 Future Meeting Dates/Topics

DISCUSSION: Kimberly Grinston reported the Board will be meeting on September 13, 2017 via conference call and meeting in October 2017 in St. Louis; Mrs. Grinston asked Board members/staff in the Kansas City area to contact the office if they would prefer a flight to St. Louis.

MOTION TO CLOSE 4:00 P.M.

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

Anita Parran – yes     Christina Lindsay – yes

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 6:12 p.m.

ITEM #5 Review of August Newsletter Draft

DISCUSSION: After discussion with legal counsel, the Board agreed to the following newsletter changes by consensus:

- **Labeling:** For distributed items, the label should include the name, lot # and expiration date. If dispensed, a patient name is not required if the patient refuses to provide one.
- **Naloxone:** Board consensus to include a newsletter statement indicating the Board will continue to research/review whether a drug distributor license is required if naloxone sales exceed 5% of the pharmacy’s prescription drug sales in the previous year. Until a final decision is reached, the Board will not require a drug distributor license.

MOTION TO ADJOURN

At approximately 6:19 p.m., a motion was made by Douglas Lang, seconded by Barbara Bilek, to adjourn the August 9, 2017, open session conference call meeting. Motion passed 3:0:0:2 by roll call vote as follows:
Anita Parran – yes       Christina Lindsay – absent

The meeting was adjourned.

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KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved: