MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

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

December 19, 2017
1:30 p.m.

Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 1:30 p.m. on December 19, 2017 via conference call. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 MO Blvd., Jefferson City, Missouri at 1:30 p.m. on December 19, 2017.

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

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

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

December 19, 2017
1:30 p.m.

OPEN SESSION AGENDA

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

2. Roll Call

3. Proposed Changes in Nonresident Pharmacy Rules

4. NABP Recommendation of the Task Force on the Regulation of Telepharmacy Practice

5. SB 501 Review of Proposed Changes to 19 CSR 30-20.100 (Pharmacy Services and Medication Management)

6. Executive Director Updates
   a. Red Tape Review
   b. EO Review

7. Future Meeting Dates/Structure

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

9. Adjournment
within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2200—State Board of Nursing
Chapter 4—General Rules

PROPOSED RESCISSION

20 CSR 2200-4.029 MNIT Administrator. This rule established the qualifications and duties of the MNIT administrator.

PURPOSE: This rule is being rescinded because the Missouri Nurse Intervention and Treatment Program (MNIT) has never been used to monitor licensees.


PUBLIC COST: This proposed rescission will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rescission will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rescission with the State Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075, or via email at nursing@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

20 CSR 2220-2.025 Nonresident Pharmacies. The board is amending sections (1), (2), and (3).

PURPOSE: This amendment updates and clarifies requirements for nonresident pharmacies.

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

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

(A) Maintain a pharmacy license in good standing from the state in which the nonresident pharmacy is located;
(B) Submit an application as provided by the Missouri Board of Pharmacy for licensure in compliance with [4 CSR 2220-2.020(2) and (3)] 20 CSR 2220-2.020(2), (3), (9), and (10);
(D) Submit a copy of the state pharmacy license from the state in which the nonresident pharmacy is located; [and]
(E) Submit a copy of the state and federal controlled substance registrations from the state in which it is located, if controlled substances are to be shipped into Missouri. If controlled substances will be shipped into Missouri, submit a copy of the applicant’s federal controlled substance registration and, if applicable, a copy of the applicant’s state controlled substance registration from the state where the applicant is located;
(F) If the designated pharmacist-in-charge does not have a current and active Missouri pharmacist license issued by the board, submit an official verification from the state board of pharmacy or equivalent state pharmacist licensing agency verifying that the designated pharmacist-in-charge holds a current and active pharmacist license in the state in which the nonresident pharmacy is located;
(G) Submit a copy of the applicant’s most recent pharmacy inspection by the applicant’s resident state board of pharmacy or its equivalent state regulatory body. The inspection must have occurred within the last eighteen (18) months for sterile compounding pharmacy applicants or within the last twenty-four (24) months for all other pharmacy applicants. If a state inspection is unavailable, an inspection by the Missouri Board of Pharmacy or from the Verified Pharmacy Program (VPP) of the National Association of State Boards of Pharmacy may be accepted.

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


PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will save private entities approximately five thousand two hundred seventy-eight dollars ($5,278) annually for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation, and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the Missouri Register. No public hearing is scheduled.
### FISCAL NOTE
PRIVATE COST

I. **Department Title:** Department of Insurance, Financial Institutions and Professional Registration  
   **Division Title:** State Board of Pharmacy  
   **Chapter Title:** General Rules

<table>
<thead>
<tr>
<th>Rule Number and Title</th>
<th>20 CSR 2220-2.025 (Nonresident Pharmacies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Rulemaking</td>
<td>Proposed Amendment</td>
</tr>
</tbody>
</table>

II. **SUMMARY OF FISCAL IMPACT**

<table>
<thead>
<tr>
<th>Estimate of the number of entities by class which would likely be affected by the adoption of the rule</th>
<th>Classification by types of the business entities which would likely be affected</th>
<th>Estimate in the aggregate as to the cost of compliance with the rule by the affected entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>203</td>
<td>Non-Resident Pharmacy Applicants</td>
<td>$5,278 (Recurring annually over the life of the rule)</td>
</tr>
</tbody>
</table>

III. **WORKSHEET**

<table>
<thead>
<tr>
<th>Estimated # of Non-Resident Pharmacy Applicants</th>
<th>Description of Costs</th>
<th>Calculation of Estimates</th>
<th>TOTAL COSTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>203</td>
<td>Non-resident pharmacist-in-charge license verifications</td>
<td>($25 verification fee x 203 pharmacists)</td>
<td>$5,075 (Recurring annually over the life of the rule)</td>
</tr>
<tr>
<td>203</td>
<td>Copy of state inspection</td>
<td>($0.10 per page x 10 pages x 203 non-resident pharmacy applicants)</td>
<td>$203 (Recurring annually over the life of the rule)</td>
</tr>
</tbody>
</table>

**TOTAL ESTIMATED ANNUAL COSTS FOR THE LIFE OF THE RULE** $5,278
IV. ASSUMPTIONS

The following estimations were used to calculate private fiscal costs:

1. Based on FY 12 – FY 16 statistics, the Board estimates an average of two-hundred and ninety (290) new pharmacy applications will be received annually. Based on current licensing trends, the Board further estimates 70% of the two-hundred and ninety (290) new pharmacy applicants will be submitted by non-resident applicants (approximately 203 non-resident pharmacy applicants).

2. License verification fees vary by state. Based on prior discussions with licensees and other state agencies, the Board estimates other states may charge an average non-resident pharmacist license verification fee of twenty-five dollars ($25). Significantly, an increasing number of states provide free online official license verifications that would be acceptable under the proposed rule amendment. Accordingly, estimated costs may be significantly lower.

3. The Board estimates the average inspection report required by the rule will not exceed ten (10) pages. Copy costs are based on currently authorized fees for copying public records under 610.026, RSMo.

4. The Board anticipates the number of non-resident pharmacy applicants will remain consistent over the life of the rule. Total estimated costs may vary with inflation and increase at the rate projected by the Legislative Oversight Committee.
PROPOSED AMENDMENT

19 CSR 30-20.100 Pharmacy Services and Medication Management [in Hospitals]. The department is amending the title of the rule and the Purpose statement; deleting sections (8), (12), (20), (21), (34), (35), and (40) and renumbering thereafter; adding new sections (16), (27) and (28); and amending sections (1), (2), (3), (5), (6), (7), (33), (36) through (39), and the new sections (9) through (26), (29) and (32).

PURPOSE: This amendment updates language throughout and places additional policy and procedure development requirements regarding: pharmacy director responsibilities; pharmacy technician personnel training records; physician review of orders and patient medication profile; medication disposal and recall procedures; and safe handling of compounded and hazardous medication. This amendment also clarifies the requirements associated with policy and procedures related to medication storage and distribution systems, inventory schedules, and medication administration to hospital patients.

PURPOSE: This rule establishes the requirements for pharmacy services and medication management in a hospital to ensure optimal selection, safe use, and security of medications.

(1) There shall be evidence of the education, training, experience, and demonstrated competency for all duties assigned in the pharmacy technicians' personnel records.

(2) In addition to other authorized duties, a pharmacy technician may perform the following duties:

(A) Verify the final product prepared by another pharmacy technician when a pharmacist is present.

1. The pharmacy technician shall have a current certificate issued by the Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians or their successor organizations; and

2. The pharmacy technician shall have documented competency in final product verification as attested by the director of pharmacy.

3. A pharmacy technician shall not be authorized to verify the final product of compounded medications or the repackaging activities of another pharmacy technician.

(B) Perform assigned duties under visual and electronic supervision of a pharmacist at a remote site, including, final product verification. Documentation of electronic final product verification shall be maintained at the dispensing site.

1. The pharmacy technician shall have a current certificate issued by the Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy...
Technicians or their successor organizations, and;

2. The pharmacy technician shall have documented competency in the assigned responsibilities being performed remotely as attested by the director of pharmacy.

3. The director of pharmacy is responsible for developing and implementing standards to ensure adequate supervision of electronically supervised technicians.

(3) An intern pharmacist licensed by the Board of Pharmacy may also perform any activity authorized for pharmacy technicians pursuant to this rule.

(4) Persons involved in compounding, repackaging, dispensing, administration and controlled substance disposal shall be identified and the records shall be retrievable. Retention time for records of bulk compounding, repackaging, administration and all controlled substance transactions shall be a minimum of two (2) years. Retention time for records of dispensing and extemporaneous compounding, including sterile medications, shall be a minimum of six (6) months.

(5) All variances, discrepancies, inconsistencies or non-compliance involving controlled substances—including inventory, audits, security, record keeping, administration, and disposal—shall be reported to the director of pharmacy services for review and investigation.

(6) Patient medications may be received from an authorized outside provider. The medications shall:

(A) Be delivered directly to the pharmacy and not to a patient care area unless the pharmacist is not available; and

(B) When a pharmacist is present, medication shall be identified, determined suitable for use and documented by the pharmacist. When a pharmacist is not present, medication shall be identified and documented by an authorized practitioner. Unused doses of medication shall be identified by the pharmacist when the pharmacist is present.

(C) The pharmacy may compound, repackage or re-label medications received from an outside provider, including prescriptions dispensed by a pharmacy, as necessary for proper distribution and administration. Records of compounding, repackaging or relabeling of prescriptions dispensed by a pharmacy shall allow identification of the original prescription.

(7) Sample medications, if allowed, shall be received and distributed only by the pharmacy.

(8) Medications may be provided to patients for use outside the hospital, by persons other than the pharmacist.

(A) When the patient is a registered patient of the emergency department or is being discharged from the hospital:

1. Medications shall be provided according to the hospital’s policies and procedures, including:
   a. circumstances when medications may be provided;[.]
   b. practitioners authorized to order;[.]
   c. specific medications [and];
d. limited quantities; 
ed. prepackaging and labeling by the pharmacist; 
f. final labeling to facilitate correct administration; 
g. delivery; 
h. counseling; and  
i. a transaction record.

2. Medications shall be labeled with the date, patient’s name, prescriber’s name, name and address of the hospital, exact medication name and strength, instructions for use and other pertinent information;

3. Medications may be provided only when prescription services from a pharmacy are not reasonably available. Reasonably available includes a pharmacist on duty in the hospital or a community pharmacy that is reasonably accessible to the patient;

4. The medication provided shall be limited to urgently needed treatment;

5. The quantity of medication provided shall be limited to the amount necessary until pharmacy services are available;

6. The provisions of paragraph (A)3 and paragraph (A)5 of this subsection shall not apply when the patient is being treated for an acute condition and it is believed that the immediate health and welfare of the patient and/or the community are in jeopardy. The quantity limit may be extended to provide single-course therapy; and

7. Final labeling, delivery and counseling shall be performed by a pharmacist, the prescriber or a registered nurse, except that final labeling and delivery may be performed by an automated dispensing system.

(B) Automated dispensing systems may be used in accordance with all requirements of this section:

1. When the automated dispensing system is controlled by the prescriber it may be used only during times when no pharmacy services are reasonably available, except as allowed in paragraph (A)6 of this section.

2. When the automated dispensing system is controlled by a pharmacy according to regulations of the Missouri Board of Pharmacy, including, but not limited to 20 CSR 2220-2.900.

(C) Medications in multidose containers that were administered to or used for the patient during the patient’s hospital stay may be sent with the patient at discharge when so ordered by an authorized practitioner.

1. Examples of multidose medication containers include, but are not limited to, inhalers, ointments, creams, medications requiring the original container for dispensing, insulin pens, eye drops, ear drops and infusions that are currently connected to the patient’s infusion device.

2. Written instructions for use shall be provided by a pharmacist, prescriber or registered nurse at the time of discharge.

3. Controlled substances shall not be sent with the patient, except that controlled substance infusions or continuous delivery systems currently connected to the patient may be sent as follows:

   (a) The medication is necessary for administration during transport of the patient; and  
   (b) The quantity of controlled substance sent is documented in the patient’s medical record by the person sending the medication.

(9) The director of pharmacy services or his/her pharmacist designee shall be an active member of the pharmacy and therapeutics committee or its equivalent, which shall advise the medical
staff on all medication matters.

(10) Medications shall be ordered only by practitioners who have independent statutory authority to prescribe or who are authorized to order medications by their professional licensing agency as provided by state law. Authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law.

(11) Medications in the possession of the patient at time of admission shall be given to the patient’s representative unless there is an identified need to retain them.
   (A) Medications that are not given to the patient’s representative and that are not to be administered shall be documented, sealed and stored in a locked area accessible only to individuals authorized to access medications.
   (B) Controlled substances shall be security sealed and stored in a locked area accessible only to individuals authorized to administer controlled substances or to authorized pharmacy personnel.


PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) annually.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed amendment with the Missouri Department of Health and Senior Services, Division of Regulation and Licensure, Jeanne Serra, Division Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.
See 536.175; The Bd also

338.100, 338.140 and

338.100, 338.140 and

338.140, 338.220 and

338.210 and 338.280

338.140 and 338.240

338.010, 338.095, 338.100 and 338.140

7/30/2016 338.140 and 338.280

8/28/2006 338.210 and 338.280

8/28/2006 338.140

620.010.15(6)

DOES THE CURRENT

REQUIREMENT

MORE STRINGENT THAN THE

FEDERAL RULE? (Y/N)

YES NO

(see comments)

DOES A PROCESS AND SCHEDULE

EXIST TO MEASURE THE

EFFECTIVENESS OF THE

RULE? (Y/N)

YES NO (partially)

IS THE RULE...

RELEVANT?

(Y/N)

YES NO

DOES THE RULE...

ENVIRONMENTAL

(Y/N)

YES NO

WAS THE RULE...

APPROVED BY THE BOARD?

(Y/N)

YES NO

DO THE COSTS...

OUTWEIGH THE BENEFITS OF

THE RULE? (Y/N)

YES NO

DID THE RULE...

BE AMENDED OR RESCINDED?

(Y/N)

YES NO

IS THE RULE...

UNLESS AND UNLESS ADOPTED

BY THE BOARD? (Y/N)

YES NO

WERE ANY COMMENTS

RECEIVED DURING THE 60-

DAY COMMENT PERIOD?

PUBLIC HEARINGS OR OTHERS?

(Y/N)

YES NO

SHOULD THE RULE...

BE AMENDED OR RESCINDED?

(Y/N)

YES NO

COULD THE

STATUTE BE

RESCUED?

(Y/N)

YES NO

SPENDABLE SAVINGS BE SUBTRACTIONAL?

(Y/N)

YES NO

DO THE COST BUDGET

MEASURE THE EFFECTIVENESS

OF THE RULE?

(Y/N)

YES NO

DO THE COSTS...

BASED ON A COST-BENEFIT

ANALYSIS? (Y/N)

YES NO

IS THE RULE...

BASED ON ADVERSELY

AFFECT Mmissouri CITIZENS?

(Y/N)

YES NO

WAS THE RULE...

MET WITHIN A 60-DAY PERIOD?

(Y/N)

YES NO

DOES THE RULE...

DURING THE 60-DAY COMMENT

PERIOD? (Y/N)

YES NO

DO THE COSTS...

EXCEED THE BENEFITS OF

THE RULE? (Y/N)

YES NO

WAS THE RULE...

MET WITHIN A 60-DAY PERIOD, PUBLIC

HEARINGS OR OTHERS?

(Y/N)

YES NO

IS THE RULE...

UNLESS AND UNLESS ADOPTED

BY THE BOARD? (Y/N)

YES NO

DO THE RULE...

BE AMENDED OR RESCINDED?

(Y/N)

YES NO

IS THE RULE...

UNLESS AND UNLESS ADOPTED

BY THE BOARD? (Y/N)

YES NO
The Board reviewed in 4/17 and 6/17; Revision held pending recommendations/suggestions from the Board's Long-Term Care Working Group.

The Board reviewed the rule in 10/17 and is researching national standards to ensure consistency and patient protection. A revision is anticipated in 2017.

This is a new rule that was promulgated in 3/17; No substantive revisions are needed at this time. However, an amendment has been filed to comply with Health Tape requirements.

This rule incorporates national due process requirements and is consistent with national standards. The rule was promulgated in 2016 and finalized in 2017; Federal guidelines are anticipated that may impact the rule.

The Board anticipates updating the rule in the future, however, no substantive changes are needed at this time. An amended rule will be effective on 1/30/18.

No substantive changes are needed at this time. The Board anticipates updating the rule in the future.

Revision held pending recommendations/suggestions from the Board's Long-Term Care Working Group.

A final draft is anticipated in spring 2016.

Substantive changes are needed at this time. The Board anticipates updating the rule in the future.

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A final draft is anticipated in spring 2016. Schedule in 2016.


Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016.

Schedule in 2016. A revised draft was filed in 2016 and finalized in 2017; Federal guidelines are pending that will impact the rule. The rule anticipates a comprehensive revised draft that will harmonize with national standards.

Schedule in 2016.

Schedule in 2016. A revised draft was filed in 2016 and finalized in 2017; Federal guidelines are pending that will impact the rule. The rule anticipates a comprehensive revised draft that will harmonize with national standards.

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<table>
<thead>
<tr>
<th>Date</th>
<th>Section</th>
<th>Proposed Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/30/2012</td>
<td>338.140, 338.145, 338.148, 338.155, 338.160, 338.165, 338.168 and 338.170</td>
<td>NO YES ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO NO YES (see comments) NO</td>
</tr>
<tr>
<td>3/30/2012</td>
<td>338.110, 338.140 and 338.145</td>
<td>NO YES ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO YES YES NO</td>
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<td>8/28/2006</td>
<td>338.140 and 338.250</td>
<td>NO NO ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO YES NO YES NO</td>
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<td>10/20/2007</td>
<td>338.140, 338.200, 338.220 and 338.240</td>
<td>NO NO ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO YES YES NO</td>
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<td>1/30/2014</td>
<td>338.250 and 338.260</td>
<td>NO NO ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO YES YES NO</td>
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<td>4/2/2016</td>
<td>338.013, 338.140, 338.148, 338.155, 338.160, 338.165, 338.168 and 338.170</td>
<td>YES NO ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO NO YES NO NO</td>
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<td>8/28/2006</td>
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<td>NO NO ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO NO YES NO NO</td>
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<td>8/28/2006</td>
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<td>NO NO ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO NO YES NO NO</td>
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<td>5/30/2016</td>
<td>338.250, 338.280 and 338.330, 338.333, 338.335, 338.337 and 338.350</td>
<td>YES NO ADMINISTRATIVE N/A YES NO Yes 536.175; The Bd also adopted a rule review schedule in 2016 YES YES NO NO NO YES NO NO</td>
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<tr>
<td>Date</td>
<td>Section</td>
<td>Administrative</td>
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<tr>
<td>8/30/2018</td>
<td>338.010, 338.140, 338.220, 338.280</td>
<td>NO</td>
</tr>
<tr>
<td>8/26/2016</td>
<td>338.095</td>
<td>NO</td>
</tr>
<tr>
<td>10/19/2016</td>
<td>338.141, 338.146 and 338.220</td>
<td>NO</td>
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<tr>
<td>6/30/2015</td>
<td>338.189, 338.190 and 338.220</td>
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<td>338.010, 338.140 and 338.220</td>
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<td>8/30/2013</td>
<td>338.010, 338.140 and 338.280</td>
<td>NO</td>
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By statute, this rule is required to incorporate national Red Tape requirements. No revisions are proposed at this time.
Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 1—Organization and Description of Board

SHALL= 9
MUST= 0

[100% REDUCTION]

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.

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 establish 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:

   1. Temporary or mobile pharmacy facilities shall 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 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.
(4) 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.

(5) 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.

(6) 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.

(7) 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.

(8) 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.

(9) 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.

(10) 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.


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 is 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 inoperable 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.
(10) 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.

(11) 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.

(12) 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.

(13) The provisions of this rule shall not conflict with 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.

(14) 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.


20 CSR 2220-2.120 Transfer of Prescription Information for the Purpose of Refill

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.

**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, 1985. Amended: Filed
Amended: Filed July 28, 2000, effective Jan. 30, 2001. Moved to 20 CSR 2220-2.120, effective

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. 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 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)(3) 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) Normal procedures for completing field investigations and assimilating other pertinent information will be followed;

   (B) 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—a 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.


Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

SHALL= 63/42
MUST= 1/1
[32.8% Reduction]

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 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.

(F) 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.

(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 shall not be limited to, the following conditions/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;
9. 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

10. 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.

(E)(D) 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.

(F)(E) 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.

(G)(F) 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 includes 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.

(H)(G) 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.

SHALL = 5/4
MUST = 1

[20% Reduction]

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 may only be released to—
   (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 220-4.020 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 document 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).

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

SHALL= 26/13
MUST= 0
[50% Reduction]

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 may 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 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, including, 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)(11) 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 do 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.


Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

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 2220-2.010(1)(H), law or the rules of the Board; nor does it relieve pharmacists from their duty to provide patient counseling as required by 4 CSR 2220-2.190.


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” 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.


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) 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.

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)(1) 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 will 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 will 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.
(G) 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.


Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 5—Drug Distributor

SHALL = 33/13
MUST = 8/3

[60% Reduction]

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 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 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 may 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 may 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 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 is required 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 with 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. The board shall issue final action by the Board 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.


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 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 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 2220-5.040 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 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).


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 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.


[***REC: RESCIND THE ENTIRE RULE***]

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.


Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

SHALL= 13/5
MUST= 1/1

[ 57% Reduced]

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 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. This rule does not 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 may only work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.


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 does 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 will 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 may 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 shall 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 will 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.


**Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION**

**Division 2220—State Board of Pharmacy**

**Chapter 7—Licensing**

**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 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 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.


Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 7—Licensing

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 will review the application and determine the candidate’s eligibility to test. Applications shall will 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 to complete the required one thousand five hundred (1,500) hours required before for 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 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 is 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.


20 CSR 2220-7.050 License Transfer/Reciprocity

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 and 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.

SHALL= 17/10
MUST= 1/1

[38% Reduced]

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 and 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 includes:
      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—may 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.


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 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 may not practice pharmacy in the state of Missouri until the license has been renewed by the board. To renew an expired license, the holder shall file a renewal application with the board and shall 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 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 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 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 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 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 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 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.