

Meeting Notice

Missouri Board of Pharmacy Hospital Advisory Group Conference Call

**September 28, 2016 2:00 pm to 4:00 pm
Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109**

Notice is hereby given of the above open conference call meeting. Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy's Hospital Advisory Group is authorized to close meetings, records and votes pursuant to Section 610.021(1).

The Group may go into closed session at any time during the meeting pursuant to § 610.021.(1) for purposes of legal advice. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

If any member of the public wishes to attend the meeting, s/he should be present at the Division of Professional Registration, Main Conference Room, 3605 Missouri Blvd, Jefferson City, Missouri, at 2:00 pm on September 28, 2016.

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.

Please see attached tentative agenda for this meeting.

TENTATIVE AGENDA
September 28, 2016 2:00 pm to 4:00 pm

Missouri Board of Pharmacy
Hospital Advisory Group
Meeting

Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109

1. Welcome & Introductions
2. Approval of Minutes
3. Board Updates
4. Department of Health Updates
5. Review of Administration by Medical Prescription Order Rule
6. Class-B Guidance Document
7. Potential Hospital Guidance Document
8. Selection/Discussion of Future Agenda Topics
9. Future Agenda Meeting/Schedules
10. Public Questions/Comments

OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

June 3, 2016

The Missouri Hospital Advisory Committee met in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed.

Committee Members Present

Bert McClary, R.Ph., Chairman
Daniel Good, R.Ph., Member
James Gray, R.Ph., Member
Colby Grove, R.Ph., Member
Neil Schmidt, R.Ph., Member
Greg Teale, R.Ph., Member

Committee Members Absent

Kevin Kinkade, R.Ph.,

Staff Present

Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector

Others Present

Barbara Bilek, Board Member
Sarah Willson, Missouri Hospital Association
Julie Creach, Missouri DHSS
David Wolfrath (MSHP liaison)

Chairman McClary opened the meeting at 10:01 a.m. and attendees were introduced.

Agenda Item # 1: Kimberly Grinston reported draft minutes from the April 11, 2016 and May 6, 2016 meetings have been included for review and approval. Greg Teale indicated Kevin Kinkade was incorrectly listed as chairman in the April minutes. No recommended changes were suggested to the May minutes. **A motion was made by James Gray, seconded by Greg Teale, to approve the April 11, 2016, minutes without the chairman designation for Kevin Kinkade. The motion passed 5:0:0:1 with roll call vote as follows:**

James Gray – yes

Colby Grove- yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Kevin Kinkade - absent

A motion was made by Neil Schmidt, seconded by Daniel Good, to approve the May 6, 2016, minutes as presented. The motion passed 5:0:0:1 with roll call vote as follows:

James Gray – yes

Colby Grove- yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Kevin Kinkade - absent

Agenda Item # 2: Bert McClary suggested discussing this agenda item with agenda items # 6 and #7.

Agenda Item # 3: Kimberly Grinston reported on recent Board activities. Ms. Grinston noted the Board was hosting a diversion conference and also a free ethics webinar for pharmacists. Greg Teale asked if regulators are seeing more diversion in retail pharmacy settings or in hospitals. Tom Glenski indicated the majority of diversion cases that the inspectors see are not hospital related. Neil Schmidt asked how soon does the Board contact a hospital when there's been a diversion. Tom Glenski indicated diversions are usually reported with an employee disciplinary action notice. Mr. Glenski commented that most inspectors will contact the hospital in two (2) weeks depending on their schedules and that the vast majority of investigations are completed within ninety (90) days. To avoid a conflict, Mr. Glenski indicated inspectors may wait to make contact if the hospital is conducting an internal investigation. Greg Teale reported hospitals in other states have experienced significant losses; James Gray agreed that diversion is a high risk point for hospitals. Julie Creach asked if Mike Boeger from BNDD should be invited to speak to the group. General consensus was to invite Mr. Boeger to a future meeting.

Agenda Item # 4: Julie Creach reported the DHSS rule revision working group met on May 5, 2016, and reviewed the Committee's suggested changes. Ms. Creach reported some of the suggested changes were not addressed in the hospital pharmacy rule because the suggestion was included/addressed in the proposed DHSS definitions rule. Ms. Creach indicated DHSS General Counsel still needs to review the proposed rules before they are forwarded to the Governor's office for final approval. Ms. Creach reported the proposed rules would likely be reviewed by the new Governor.

Ms. Creach also reported that DHSS may be modifying the hospital construction requirements based on recently passed 2016 legislation. Bert McClary asked for additional information on the construction changes. Sarah Willson with MHA indicated the changes were suggested before her tenure but noted the current construction standards are outdated and may not have been revised since 1982. Ms. Willson indicated MHA worked with DHSS on the language and noted the current legislation requires the most updated life safety requirements from the National Fire Protection Association and is consistent with CMS' most recent updates to the 2012 safety codes.

Ms. Willson also reported MHA felt it could not adopt/endorse all of the Facility Guideline Institute's (FGI) hospital design and construction standards at this time. MHA will work with DHSS and the Missouri Society for Healthcare Engineering to review FGI

standards and find a solution. Julie Creach indicated DHSS previously intended on adopting the FGI standards but will now need to draft a rule that may incorporate all or portions of the FGI standards. Sarah Willson commented that nothing prevents an entity from voluntarily following the FGI guidelines or a more current standard which is what many entities have done. However, Ms. Willson spoke favorably of DHSS being able to enforce and survey to newest standards.

Mr. McClary noted the new standards may affect sterile compounding areas and medication rooms but noted that sterile compounders should not be detrimentally impacted given that DHSS proposed rules adopt and require compliance with USP Chapter 797.

Agenda Item # 5: Tom Glenski reported the webinar is currently scheduled for August 25, 2016. Greg Teale commented that he's recently received inquiries regarding what falls under the hospital's license and what is considered a Class-B activity. Sarah Willson indicated that defining the hospital premises is still a major area of confusion and suggested that DHSS or the Board create a "top 10" list of things to look for when trying to make the distinction.

Greg Teale commented that many times pharmacy may not be informed in a timely manner when new buildings are being added and noted that hospital administration may not be aware of the legalities/licensing issues surrounding the hospital premises. Tom Glenski cautioned that pharmacies should contact DHSS to verify what areas are part of the licensed hospital premises. Mr. Glenski noted that buildings/areas do not automatically qualify as part of the licensed premises just because they meet the statutory definition. Instead, Mr. Glenski noted DHSS has to be notified and the building/area has to be officially recognized by DHSS as part of the licensed area. Bert McClary commented the hospital premises question has been an issue for some time and suggested the Board and DHSS create some form of guidance document.

Bert McClary asked if the Board/DHSS wanted the Committee to review the proposed webinar questions and answers. Kimberly Grinston indicated proposed webinar questions could be brought to a future meeting.

Agenda Items # 6 and #7: Bert McClary indicated these items could be grouped with the administration rule and once again suggested that the Board draft a guidance document that gives criteria for determining what pharmacy services are under the Board's jurisdiction. Mr. McClary suggested the guidance document also address areas of conflict/inconsistency between DHSS standards and Board standards. Mr. McClary indicated further guidance on the Board's regulatory jurisdiction is needed for not just hospitals/health systems but also other health care entities. Mr. McClary noted the previous MHA case against the Board did not address other practice settings and asked how entities like long-term care facilities who may want their own pharmacy would be regulated. Mr. McClary also inquired about Board jurisdiction over ambulatory surgical centers where pharmacy services are provided. Greg Teale noted that with current

reimbursement issues, the jurisdictional question may become more common. Sarah Willson agreed especially for acute and post-acute care providers.

Additional discussion was held. Greg Teale commented that the dual licensure requirements have become problematic and that pharmacy services must be safe and efficient to practice. Sarah Willson indicated that having a pharmacist involved in dispensing activities is the safest practice and that removing the pharmacist is not in the patient's best interest. Bert McClary once again suggested that the Committee focus on the appropriate rules for hospital related entities and noted the administration rule is a good example of Board rules that may impact different licensing settings. Mr. McClary noted these practice settings could be simply identified as "health care entities" if defined properly.

Kimberly Grinston suggested that defining "health care entity" too broadly could slow down Board resolution of the issue. Neil Schmidt indicated he previously preferred the term "health system." Sarah Willson suggested that representatives from these other practice settings may need to be added to the discussion.

The following additional discussion was held on the administration by medical prescription order rule:

- Bert McClary asked if the definition of "health care entity" in the rule was sufficient or if it should be limited to just licensed entities. Mr. McClary indicated he always presumed that any place that offers or practices onsite direct patient care/clinical services would need to be licensed. Kimberly Grinston asked if the Committee was attempting to address pharmacists administering under the hospital's authority. James Gray advised the Committee should not make the rule too broad and suggested referencing "health system" as an umbrella term. However, Mr. Gray cautioned the definition should not be so complicated that it couldn't be enforced. Sarah Willson commented that the reason for exempting hospitals from Board requirements is because they are extensively regulated by the Joint Commission and CMS. Ms. Willson suggested that other practice settings in newer business models may not have a proven track record. Ms. Willson commented that exemptions for emerging business models outside of a hospital setting may be too broad of an application at this time. However, Bert McClary commented Missouri's rules should not impose harsher restrictions on pharmacists than other healthcare practitioners that may be handling or administering medication in the same setting.
- In further discussion, Kimberly Grinston noted the current draft administration rule focuses on who the practitioner is operating on behalf of. Tom Glenski suggested limiting section (10) of the draft to individuals operating on behalf of a health care entity. James Gray alternatively suggested including persons operating on behalf of a health care entity "or as determined by the Board" to give the Board discretion. Bert McClary asked if the rule should include the definition of hospital and hospital clinic or facility from SB 808 enacted in 2014.

Consensus to add the definitions of hospital and hospital clinic and facility from SB 808 and to add “other facilities recognized by the Board.”

- Committee members asked that the rule clarify that administration policies and procedures can be maintained as part of the hospital’s policies/procedures. A suggestion was also made that the rule allow the required administration notifications to be maintained in a common electronic record.
- Additional suggested changes are highlighted in Appendix A.

Agenda Item #8: Kimberly Grinston reported the office is working on a draft guidance to address many of the jurisdictional and practice concerns the Committee previously discussed. Ms. Grinston indicated the draft guidance would be returned to the Committee for additional review/comment at a future meeting. Greg Teale indicated he surveyed his peers and asked them to rate their pharmacy related concerns by priority/level of importance. Mr. Teale indicated the following concerns were submitted:

1. Labeling: Concerns were raised that the Class-A labeling requirements were inappropriate for hospital facilities- many of whom are dispensing for immediate use. It was reported that entities such as infusion clinics may be using the hospital’s labeling system and wouldn’t have information like the pharmacy’s address or phone number on the label.
2. Filing Orders: Concerns were raised that medication orders are not kept in a regular prescription file as required for retail pharmacies.
3. Medication Therapy Services/Collaborative Drug Therapy Agreements: Concerns were raised that the MTS rules require an agreement between the pharmacist and physician although some Class-B pharmacies may be using a P&T protocol. Concerns were also expressed about the inconsistent standards for pharmacists who may be fluctuating between DHSS regulated settings and Board regulated settings. Greg Teale commented the current requirements are both burdensome and confusing when providing patient care.
4. Automated Cabinets: Concerns were raised that pharmacy controlled automated cabinets may be the primary means of distribution for some Class-B pharmacies in lieu of transferring stock to a cabinet for physician dispensing. James Gray noted these medications stay under the control of the pharmacy. Greg Teale indicated the automated cabinets use technology to enhance accuracy and prevent diversion and that cabinet activity is verified by a pharmacist. Mr. Teale asked the Board to consider how these cabinets may be operated lawfully and still stay under pharmacy control.

Additional discussion was held regarding remote/video monitoring of technician activities. Tom Glenski reported the Board has previously indicated that remote final product verification is not allowed. James Gray suggested that the Board reconsider this issue and asked what the Board’s concerns would be if the data shows a higher degree of accuracy with remote/electronic verification. Tom Glenski added the Board has been reluctant to address expanded duties for technicians until technician education or training requirements are in place.

5. Pharmacy Access: Concerns were raised regarding access to the pharmacy by other healthcare practitioners. Greg Teale indicated there may be a need for nurses to access the pharmacy to draw doses or access medication when the pharmacy is closed. Tom Glenski indicated Missouri law says these nurses may need to be a technician but noted the Board has never officially addressed this topic for nurses entering Class-B pharmacies. Bert McClary suggested there would be value in allowing access for nursing staff and other healthcare practitioners in lieu of stocking medication outside of the pharmacy.
6. Concerns were raised regarding USP chapters 797 and 800. However, Greg Teale indicated this may not need priority consideration at this time. Tom Glenski noted the Board's requirements are generally stricter than DHSS' requirements. Mr. Glenski mentioned the previously discussed white-bagging issue and indicated the Board wrote a rule that may address this. James Gray commented there is general confusion about what is allowed under a Class-J arrangement.
7. Mr. Teale noted he will discuss the proposed webinar questions with his contact group and will try to have feedback before June 20th.

James Gray suggested that compounding issues are also a topic of concern that should be addressed. As an example, Mr. Gray indicated there may be surgery centers using compounded topicals during surgery that may ask the pharmacy to prepare a batch that is non-patient specific. Mr. Gray commented that pharmacists cannot prepare non-patient specific batches but noted that hospital-owned surgical centers can prepare non-patient specific batches without pharmacist involvement. Tom Glenski said the Board may reconsider this issue given the one (1) mile limit indicated in the most recent FDA Guidance and asked Committee members to identify other scenarios hospitals may be dealing with. James Gray suggested hospitals may need to know that pharmacies in a Class-J arrangement can compound and send non-patient specific prescription to another pharmacy.

Agenda Item #9: Bert McClary suggested the Committee could be a resource for practice questions that the Board and DHSS may receive on a regular basis. Tom Glenski said planned to review a list of questions on the webinar. Bert McClary asked Mr. Glenski to compile a list of common questions for Committee review and or guidance.

Committee Member Greg Teale left the meeting at 2:38 p.m.

Agenda Item #11: Bert McClary indicated this topic was previously discussed and asked the group to send hospital premises related questions/examples to DHSS.

Agenda Item # 12: Kimberly Grinston reported on pending legislation listed in the agenda and noted there have been extensive discussions regarding the value of a PDMP. Neil Schmidt inquired about proposed legislation that would allow pharmacists

to dispense contraceptives; Kimberly Grinston reported she does not believe the legislation passed but will update the Committee if different.

Agenda Item # 13: Bert McClary asked if Committee members still wanted to meet monthly. Committee consensus to continue monthly meetings and to schedule the next conference call on July 15, 2016 from 2:00 – 4:00 p.m. and the next full meeting for August 26, 2016, in Jefferson City.

A motion was made by Neil Schmidt, seconded by Colby Grove, to adjourn the meeting. Chairman McClary adjourned the meeting by consensus at approximately 2:59 p.m.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:

**Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care
Standards**

20 CSR 2220-6.040 Administration by Medical Prescription Order

PURPOSE: This rule establishes procedures for pharmacists to administer drugs and devices, including ~~devices~~ vaccines, pursuant to medical prescription orders.

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

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

(A) “Health Clinic or Facility”- A clinic or facility under the common control, management, or ownership of the same hospital or hospital system.

(B) “Hospital”- A hospital as defined in section 197.020.

(C) “Medical Prescription Order”- A lawful order for drugs or devices issued by an authorized practitioner within the scope of his/her professional practice which is to be dispensed or administered to the ultimate user or recipient.

~~(2)~~(3) The pharmacist may not delegate the administration to another person, except to an ~~pharmacist intern~~ intern pharmacist who has met the qualifications under subsections ~~(3)(B), (C), and (E)~~ (4)(B) - (D) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order. The pharmacist and pharmacist intern shall maintain proof of the intern’s compliance with this subsection.

~~(3)~~(4) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the state Board of Pharmacy. To file a Notification of Intent, a pharmacist must—

(A) Hold a current, ~~unrestricted~~ license to practice pharmacy in this state;

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

(C) Successfully complete a certificate program in the administration of drugs ~~accredited provided by: the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy~~ (1) a continuing education provider accredited by the Accreditation Council for Pharmacy Education (ACPE) or (2) a governmental entity, healthcare professional organization or educational institution approved by the Board. To obtain Board approval, the training program must [be taught by qualified instructors/a licensed healthcare professional and] provide instruction in: ~~.-The certificate program must cover a~~

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

~~(D) Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;~~

~~(E) Maintain documentation of the above requirements; and.~~

~~(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.~~ (E) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist shall first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized

to administer medication. Documentation of the required training shall be maintained at the pharmacy and available to the Board upon request.

~~(4)~~ (5) General Requirements.

(A) A pharmacist shall administer ~~drugs~~ vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC) ~~or in accordance with manufacturer's guidelines.~~ In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

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

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs by medical prescription order, ~~including the disposal of used and contaminated supplies and appropriate handling of acute adverse events.~~ The manual Policies and procedures shall be reviewed annually by the pharmacist-in-charge. Policies and procedures must be available for inspection by the State Board of Pharmacy or other authorized Board representative. Documentation of the annual review must be maintained in the pharmacy's records. At a minimum, the required policies and procedures must include provisions governing:

1. Drug administration procedures, including, authorized routes of administration,
2. Drug storage;
3. Pre- and post- administration assessment and counseling, including, providing vaccine information statements when applicable;
4. Biohazard waste disposal and disposal of used/contaminated supplies;
5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.

(D) Drugs must be stored within the manufacturer's labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.

(E) Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

~~(F) For pharmacists administering drugs in a, the policy and procedure review required by this subsection may be performed by the pharmacist in charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the responsible for reviewing clinical practices.~~

~~(5)~~ (6) Requirements of Medical Prescription Order. The medical prescription order from a ~~licensed prescriber~~ an authorized practitioner must contain at a minimum the following:

- (A) The name of the ~~licensed prescriber~~ authorized practitioner issuing the order;
- (B) The name of the patient to receive the drug;
- (C) The name of the drug and dose to be administered;
- (D) The route of administration;
- (E) The date of the original order; and
- (F) The date or schedule, if any, of each subsequent administration; ~~and~~
- ~~(G) A statement that the drug is to be administered by a pharmacist.~~

~~(6)~~ (7) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy.

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, ~~lot number,~~ and expiration date of the drug. The lot number shall be documented and recorded for vaccines and biologics;
4. For vaccines, ~~T~~the name and address of the patient's primary health care provider, as identified by the patient. The pharmacist shall document in the patient's immunization record if a patient's primary health care provider is unknown or not designated by the patient;
5. The ~~name or identifiable initials~~ identity of the administering pharmacist. If administered by an intern pharmacist, the identity of the intern and the supervising pharmacist; ~~and~~
6. The nature of an adverse reaction and who was notified, if applicable; ~~;~~
7. A patient's refusal or failure to remain in or return to the pharmacy as requested after vaccine administration to observe any adverse reactions; and
8. Written or electronic documentation that required notifications have been sent.

(B) All records required by this ~~regulation-rule~~ shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. Records may be securely stored offsite at a location designated by the pharmacy, provided records must be produced as provided in section (7)(C) of this rule.

(C) Production of Records. Records required by this rule shall be maintained either electronically or physically for two (2) years and shall be readily retrievable and subject to inspection by the board of pharmacy or its agents. At a minimum, records maintained at the pharmacy shall be physically or electronically produced immediately or within two (2) hours of a request from the Board or the Board's authorized designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Board and/or its authorized designee.

~~(7)~~ (8) Notification Requirements.

(A) A pharmacist administering ~~drugs~~ a vaccine pursuant to a medical prescription order shall notify the ~~prescriber within seventy-two (72) hours~~ patient's primary health care provider, if provided by the patient, within fourteen (14) days after administration of the following:

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

(B) In the event of any adverse event or reaction experienced by the patient following administration of a drug, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. The prescriber may not opt out of adverse event notification requirements.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

(D) Documentation that the required notifications have been sent must be kept at the pharmacy or other authorized location where the prescription order is maintained.

(9) Notification of Intent Refiling. A Notification of Intent to administer drugs by medical prescription order shall be refiled with the state board of pharmacy biennially along with the pharmacist's Missouri pharmacist license. To refile, a pharmacist must:

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

(B) Have successfully completed four (4) hours of continuing education (0.4 CEU) related to drugs administration. The required continuing education (CE) shall be governed by the rules of the state Board of Pharmacy governing pharmacist CE and may be used to satisfy the pharmacist's biennial pharmacist renewal CE requirements. The initial training program required by subsection (4) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within twelve (12) months prior to refiling the pharmacist's Notification of Intent.

(10) Administration in a Hospital or a Health Clinic or Facility- Pharmacists administering medication under the jurisdiction of the Board on behalf of a hospital or a health clinic or facility shall comply with the requirements of this rule with the following exceptions:

(A) A pharmacist shall be deemed in compliance with the requirements of sections (7) and (8) of this rule if the pharmacist administers drugs for or on behalf of a hospital or a hospital clinic or facility in compliance with this section and the administration is lawfully recorded in a patient medical record that is required to be maintained by the hospital or the hospital clinic or facility pursuant to state or federal law.

(B) In lieu of completing a certificate program in the administration of drugs as required by section (4) of this rule, pharmacists administering in a hospital or a hospital clinic or facility shall be trained in administration and meet all competency, training and evaluation requirements required by the hospital or hospital clinic or facility and the Missouri Department of Health and Senior Services (DHSS). At a minimum, pharmacist administration training must be similar to or include the training components identified in section (4)(C).

(C) A pharmacist shall administer vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention

(CDC). In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

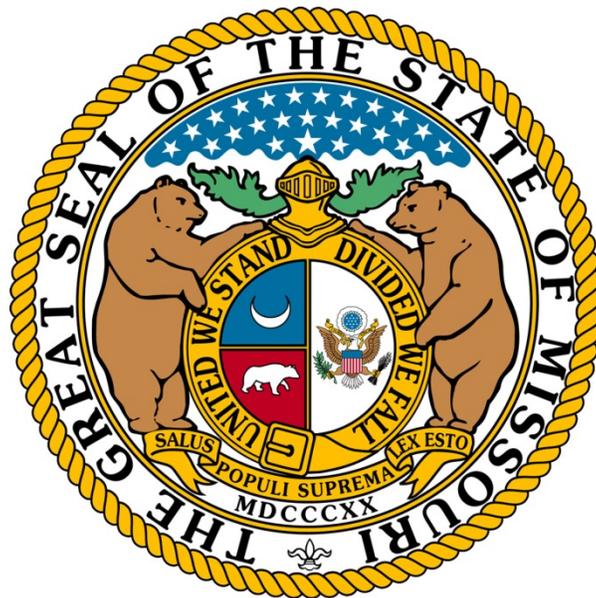
(E) The policy and procedure review required by section (5) may be performed by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the hospital responsible for reviewing clinical practices. Required policies and procedures may be maintained in or included with the governing hospital's approved policies, procedures or protocols.

(F) This section is only applicable to pharmacy services under the jurisdiction of the Board and is not applicable to hospital pharmacy services or pharmacist medication administration under the jurisdiction of the Department of Health and Senior Services.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and section 338.010.1, RSMo Supp. 2007. Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

MISSOURI BOARD OF PHARMACY



CLASS-B HOSPITAL PHARMACY GUIDANCE

***** THIS DRAFT HAS NOT BEEN REVIEWED OR APPROVED BY THE BOARD
AND MAY NOT REFLECT THE BOARD'S CURRENT POSITION/GUIDANCE*****

CLASS-B

Hospital Pharmacy Guidance

This guidance document is being provided by the Missouri Board of Pharmacy to provide compliance information for Class-B Hospital pharmacies. **This guidance is not applicable to pharmacy services regulated by and under the jurisdiction of the Missouri Department of Health and Senior Services (DHSS).**

OVERVIEW

In 2014, the Missouri General Assembly enacted SB 808 which officially established a Class-B Hospital pharmacy permit for pharmacies located in Missouri licensed hospitals and also hospital clinics and facilities. Prior to the new law, only Missouri licensed hospitals were eligible for a Class B permit. As healthcare delivery models have evolved, Missouri hospitals indicated pharmacy services were increasingly being delivered via hospital owned clinics or satellite pharmacies that were not part of the licensed hospital. The Board was informed its general pharmacy rules conflicted or hindered compliance with accreditation and other reimbursement requirements, particularly for clinics/facilities not engaged in traditional “prescription” dispensing.

The Board subsequently convened a Hospital Pharmacy Advisory Group comprised of hospital representatives to assist the Board in addressing these concerns. The Advisory Group recommended establishing a single Class-B permit class for both hospitals and hospital related clinics and facilities along with enhanced distribution/dispensing standards for Class-B pharmacies under common control or ownership.

SB 808 was subsequently enacted which officially established the current Class-B Hospital Pharmacy permit classification. SB 808 also:

- Created additional dispensing and distribution allowances for Class-B pharmacies;
- Granted DHSS and the Board of Pharmacy authority to collaborate on rules governing medication distribution and medication therapy services performed by a pharmacist at or within a hospital. This allowance does not change DHSS’ current jurisdiction over hospital pharmacy but allows the agencies to collaborate on rulemaking, and
- Established a standing Hospital Advisory Committee to advise the Board. The Advisory Committee consists of hospital representatives designated by DHSS, the Missouri Hospital Association, the Missouri Society of Health System

Pharmacists and the Missouri Pharmacy Association and a Board appointed pharmacist with experience in hospital pharmacy.

CLASS-B PERMIT REQUIREMENTS

Section 338.220, RSMo, defines a “Class-B Hospital Pharmacy” as:

- A pharmacy owned, managed, or operated by a hospital as defined by § 197.020, or
- A hospital clinic or facility under common control, management or ownership of the same hospital or hospital system. [§ 338.165.1(3); § 338.220.6].

Eligible clinics/facilities may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements (*this list is not exhaustive*). The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board’s jurisdiction.

Applicants should consult with legal counsel to determine if a hospital clinic/facility is under “common control, management or ownership of the same hospital or hospital system.” The Board cannot provide legal advice.

Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area and pharmacy activity would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses.

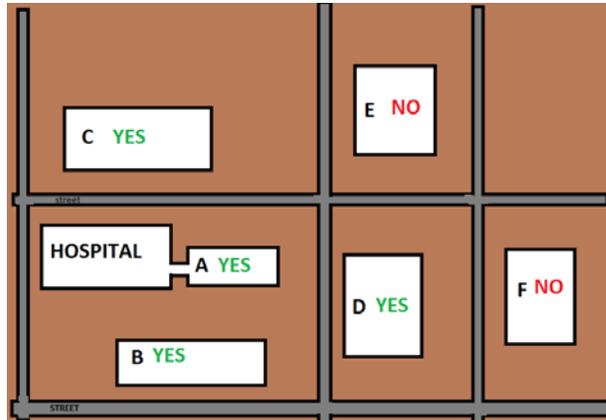
Class-B applications and related fees are available on the Board’s website. *Note: Applicants must apply for and hold any required classification for specialty pharmacy services regulated by the Board (e.g., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).*

CLASS-B LICENSURE FOR MISSOURI HOSPITALS

Under Chapter 197, RSMo, DHSS has regulatory jurisdiction over pharmacy services provided within the “[licensed premises](#)” of a Missouri hospital. A Class-B Hospital Pharmacy permit is not required for hospitals “solely providing services within the practice of

pharmacy under the jurisdiction of, and the licensure granted by” DHSS. [§ 338.220.6, RSMo]. Hospitals solely providing pharmacy services under DHSS’ jurisdiction may choose to be licensed as a Class-B pharmacy although not required.

Section 197.052, RSMo, defines the hospital premises as: *“tracts of property which are adjacent but for a common street or highway, as defined in section 300.010, and its accompanying public right-of-way.”* DHSS has provided the following examples of facilities considered “adjacent but for a common street or highway” to a hospital:



According to DHSS, buildings or areas that do not meet the above definition/ requirements would not qualify as part of the hospital’s premises even though the building/area may be:

- Part of the hospital’s campus
- Under the same CMS Certification Number (CCN), or
- Under the same ownership



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

DHSS has advised that the hospital premises may include more than just “inpatient” areas. For example, other hospital areas such as emergency departments, infusion clinics, urgent care facilities, ambulatory surgery centers, physical therapy departments or other “outpatient” service areas may be included, provided the facility or department meets the hospital premises definition above. *Note: Additional DHSS regulatory requirements may apply (e.g., DHSS construction standards/life safety requirements).*

Examples of pharmacy services under DHSS' jurisdiction would include, but are not limited to:

- Dispensing or distributing medication for use or administration to patients within the same DHSS licensed premises regardless of billing status ("inpatient" vs. "outpatient"). This includes dispensing or distributing to clinics or other hospital departments included within the DHSS licensed premises,
- Compounding medication within the DHSS licensed hospital premises for use or administration within the same licensed premises;
- Counseling or providing other non-dispensing pharmacy services for patients located or receiving treatment within the DHSS licensed hospital premises (e.g., DUR, medication reconciliation, order review/approval),
- Administering medication within the DHSS licensed hospital premises, and
- Initiating, modifying or dosing medication for use or administration within the DHSS licensed hospital premises (*a Board Certificate of Medication Therapeutic Plan Authority would still be required as described below*).

The Board has jurisdiction over pharmacy services provided outside of the licensed DHSS hospital premises. Examples would include, but are not limited to:

- Dispensing or distributing medication that will be used or administered outside of the DHSS licensed premises (e.g., "take-home" meds)
- Pharmacy services provided under a pharmacy's Class-B permit
- Compounding for use or administration outside of the DHSS licensed hospital premises or compounding medication outside of the DHSS licensed hospital premises regardless of patient location
- Counseling or providing other non-dispensing pharmacy services for patients located or receiving treatment outside of the DHSS licensed hospital premises (DUR, medication reconciliation, order review/approval)
- Administering medication outside of the licensed hospital premises,
- Modifying or initiating drug therapy that will be dispensed, distributed or administered outside of the DHSS licensed premises, and
- Pharmacy services provided at a clinic or facility that is not part of the DHSS licensed hospital premises. This would include any clinic/facility that has not been officially designated with DHSS as part of the hospital's license even if located within the hospital's building or on the hospital campus.

The Board has determined that "take-home" medication would not include a self-contained medication therapy course where administration is initially started within the DHSS licensed hospital premises and will leave with the patient. Examples would include intrathecal or 5-FU pumps that are started within the DHSS licensed hospital premises. The Board has also determine that medication sent with a patient to be used during an emergency transfer to

another facility would not be considered a “take home” medication. These services may be provided under DHSS’ jurisdiction; additional Board licensure is not required.

Additionally, DHSS rules allow licensed hospitals to send a limited supply of medication home with the patient from the hospital when pharmacy services are not reasonably available. A Board pharmacy permit is not required for these activities as authorized by DHSS rules.

All pharmacists, technicians and interns practicing in Missouri must hold an individual pharmacist, technician or intern license/registration issued by the Board regardless of practice setting. Pharmacist, technicians and interns practicing within a DHSS licensed hospital must be licensed with/registered by the Board.

DUALLY REGULATED ENTITIES

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

DHSS licensed hospitals may choose to license all or a portion of the hospital as a Class-B pharmacy. The Board would only have jurisdiction over and regulate the Class-B pharmacy services.

NON-DISPENSING ACTIVITIES

Missouri law authorizes pharmacists to perform non-dispensing activities outside of a Missouri licensed pharmacy. Specifically, 20 CSR 2220-6.055 provides a pharmacist may perform the following activities at a non-pharmacy location:

- | | |
|--|--|
| (1) Administering medication or biologicals | (7) Pharmacy compliance audits/evaluations |
| (2) Obtaining patient history/information | (8) Peer review/peer consultations |
| (3) Reviewing patient records/medical reconciliation | (9) Managing drug inventory, including purchasing and ordering |
| (4) Patient assessment/evaluation | (10) Consulting with other health care professionals |
| (5) Insurance billing and claims | (11) Patient referrals |
| (6) Drug utilization review | |

- | | |
|--|---|
| (12) Medication therapy management/medication therapy services, and | accept a prescription on the premises of a Missouri licensed pharmacy [§ 338.095.5] |
| (13) Prescription order entry/review, provided a pharmacist can only | |

A Class-B pharmacy permit would not be required for allowed non-dispensing activities, unless technicians will be assisting at the non-pharmacy location.¹

The Board has been asked if pharmacists can maintain or monitor drug storage areas/units that are located in hospital areas/facilities that are not licensed with the Board or located in other unlicensed healthcare facilities such as a private physician's office, ambulatory surgical center or an infusion clinic. Class-B pharmacies cannot store medication outside of the licensed pharmacy area, except as allowed by 20 CSR 2220-2.900 for automated dispensing systems. However, 20 CSR 2220-6.055 would allow pharmacists to monitor/maintain medication or drug storage areas *belonging to other unlicensed entities* without a Board pharmacy permit. This would include non-dispensing activities such as checking drug storage, inventorying medication, performing drug utilization reviews, medication reconciliation and counseling patients (*this list is not exhaustive*).

SCOPE OF CLASS-B ACTIVITIES

Once licensed by the Board, sections [338.165.5 and .6](#), RSMo, grant two new allowances to Class B Hospital pharmacies. Specifically, Class-B Hospital pharmacies may:

- 1) Dispense medication by prescription or by medication order, and
- 2) Distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

Dispensing by Prescription/Medication Order

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

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

¹ A Board pharmacy permit would not be required if technicians are only assisting with administering vaccines. 20 CSR 2220-6.055(6).

1. Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee, and
2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized designee at a hospital or a “hospital clinic or facility” that is under the “common control, management or ownership of the same hospital or hospital system.” [Section 338.165.1, RSMo](#)

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

The Board has been asked if a medication order may be used to dispense a self-contained medication therapy course that will be initially administered onsite but later sent home/transferred with a patient to complete/continue administration (e.g., intrathecal and 5-FU pumps). The Board has determined that a medication order may be used in these instances provided administration to the patient initially begins at the hospital or at a qualifying hospital clinic or facility.

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

[Drug Distribution by Class-B Pharmacies](#)

Section [§ 338.165.6](#) provides a Class B Hospital pharmacy may distribute medication to a “hospital clinic or facility” for patient care or treatment without a Missouri drug distributor license. Once again, a “hospital clinic or facility” is defined as a clinic or facility under common control, management or ownership of the same hospital or hospital system.

The following chart provides examples of distributions that are authorized for Class-B pharmacies without an additional Missouri drug distributor license:

Under federal law, a pharmacy may still be required to register with the DEA as a controlled substances distributor if the total dosage units of all controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed by the pharmacy during the previous calendar year.

Significantly, a Class B pharmacy may not distribute compounded preparations to other entities or distribute repackaged medication to other practitioners without being registered with the FDA.

Class-B Labeling Requirements

Section 338.059, RSMO, provides a written label must be affixed to each prescription container dispensed to a consumer indicating:

- 1) The date the prescription was filled;
- 2) A prescription number or other unique identifier;
- 3) The patient's name;
- 4) The prescriber's directions for usage;
- 5) The prescriber's name;
- 6) The pharmacy's name and address;
- 7) The exact name and dosage of the drug dispensed, and;
- 8) If a generic substitution is made, the manufacturer must be identified on the label or in the pharmacy's records by name or abbreviation. [[§ 338.059](#)].²

For controlled substance prescriptions issued by an advanced practice registered nurse (APRN) or a physician assistant (PA), the required label must also include the names of the prescribing mid-level practitioner and their supervising or collaborating physician. [[§ 195.100, RSMo](#)].

If a unique identifier is used in lieu of a prescription number, the identifier must be able to retrieve the patient's specific medication order/prescription. Board inspectors have observed instances where a unique identifier could retrieve the patient's medical record but not the specific medication order/prescription. In some cases, the same identifier was used for multiple patients. Unique identifiers should be formatted to allow retrieval of the specific dispensing record for each individual patient (e.g. a unique identifier/order #).

² Section 338.059, RSMo, does not apply to internal drug orders for hospital in-patients.

The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite administration to a patient. The Board understands labeling may be a particular issue for hospital-owned clinics/satellite pharmacies that may not use prescriptions or have software to print a traditional “outpatient” prescription label.

The Board intends on addressing this issue by rule in the future. In the interim, Board Inspectors will not cite Class-B pharmacies for violations of § 338.059’s labeling requirements if:

- 1) Medication is given to a healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy or within the licensed premises of a DHSS licensed hospital, and
- 2) The medication/prescription container labeling is accurate and complies with DHSS’ medication labeling requirements [see generally 19 CSR 30-20.100(21) which requires patient name, drug name, strength, expiration date, lot number when applicable and other pertinent information], and³
- 3) The medication/prescription container is not given to the patient for use/administration outside of the Class-B pharmacy location or DHSS licensed hospital premises. The Board will not consider a self-contained medication therapy course to have been “given to the patient for use/administration” offsite if administration is initiated within a Class-B pharmacy location or the DHSS licensed hospital premises but is continued or completed offsite (e.g., intrathecal and 5-FU pumps).

Sterile Compounding

Class-B pharmacies engaged in sterile compounding must also have a Class-H Sterile Compounding pharmacy permit. All sterile compounding for use or administration to patients outside of the DHSS licensed hospital premises must comply with the Board’s sterile compounding rules (20 CSR 2220-2.200, 20 CSR 2220-2.400). Class-B pharmacies may share sterile compounding space/equipment with a DHSS hospital (e.g., the same clean room). However, the sterile compounding area will be inspected for compliance with Board requirements.

Licensees are reminded that Class-B pharmacies may only dispense compounded sterile preparations pursuant to a patient-specific prescription or a patient-specific medication order.

Allowed Technician Activities

³ Radiopharmaceuticals must also comply with 19 CSR 30-20.100(18)

Generally, a Missouri pharmacy technician license is required for any person who has independent access to a pharmacy on a routine basis or who assists a pharmacist in the practice of pharmacy. Given the nature of hospital practice, the Board has determined that technician registration is not required for nurses and other healthcare practitioners who access Class-B pharmacy space or drug inventory that is shared with a DHSS regulated hospital pharmacy as part of their non-pharmacy job duties.

Pharmacy technicians may assist in any area of pharmacy practice that does not require the use of professional judgment by a pharmacist. [20 CSR 2220-2.700(1).] Technicians assisting in Class B pharmacy practice may not work independently and must be under the direct supervision and responsibility of a Missouri licensed pharmacist at all times. [20 CSR 2220-2.700]. All prescriptions prepared or compounded by a technician in a Class-B pharmacy must be finally verified/checked by a pharmacist, including, reconstituted products.

Medication Therapy Services

Under Missouri law, all pharmacists providing medication therapy services (MTS) must obtain a certificate of medication therapeutic authority from the Board, regardless of practice setting. [§ 338.010.4] Licensees should review the Missouri Pharmacy Practice Guide for additional MTS requirements.

As explained in the Practice Guide, an MTS certificate is not required to perform traditional pharmacist functions such as medication reconciliation or medication therapy management. A MTS certificate is only required if a pharmacist will be modifying drug/device therapy which includes:

- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different or additional strength, dose, dosage form or dosage schedule; or
- Selecting, adding or changing a new or different route of administration.

Generally, pharmacists who are dosing, modifying or initiating medication that will be dispensed, distributed or administered outside of the DHSS licensed premises would be regulated by the Board and required to comply with the Board's MTS rules and requirements. DHSS would regulate dosing, modifying or initiating medication within the DHSS licensed hospital premises (a Board MT certificate would still be required). *Note: This is a general guideline. A determination of DHSS/Board jurisdiction would depend on the specific facts.*

The Board has issued the following additional guidance for pharmacists performing MT services under the Board's jurisdiction:

1. Pharmacists must have a MT protocol with a Missouri physician that complies with 20 CSR 2220-6.080. A hospital protocol may be used to provide MT services if the protocol includes all information required by 20 CSR 2220-6.080(4) and authorizes the pharmacist to perform the services provided. A separate protocol would not be required. In lieu of individual signatures, 20 CSR 2220-6.080 allows the pharmacist and authorizing physician(s) to sign and date a statement agreeing to be governed by the hospital's protocol.
2. Pharmacists are required to notify the protocol physician within twenty-four (24) hours of modifying drug therapy or within 24-hours of an adverse event, adverse medical reaction or an adverse needle stick. The Board has determined that notifications may be maintained in an electronic medical record (EMR) that is required to be maintained by state or federal law, provided the EMR is accessible to and shared by both the physician and pharmacist.
3. In addition to a MT protocol, pharmacists performing MT services under the Board's jurisdiction must also have a prescription order from a physician authorizing them to provide MT services for the specific patient. The Board has determined that a protocol approved by a hospital's clinical care committee, pharmacy and therapeutics committee or an equivalent hospital reviewing body/committee may be used to initiate pharmacist MT services, provided the protocol is not restricted or limited to MT services within the DHSS licensed premises.⁴ By statute, the prescription order/protocol must be initiated or issued by the physician and not a nurse or physician assistant. [§ 338.010.2]
4. Generally, the authorizing physician must review the pharmacist's MT services at least once every three (3) months. For pharmacists providing MT services for, or on behalf of, a licensed hospital, the required review may be conducted by the clinical care committee, the pharmacy and therapeutics committee or by an equivalent hospital reviewing body that includes a Missouri-licensed physician (e.g., the medical staff committee).⁴

The above requirements are for services provided under the Board's jurisdiction. Please consult DHSS requirements for services provided under their jurisdiction.

⁴ Note: This allowance would also apply to pharmacists providing MT services for, or on behalf of, a state or federally licensed hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility or a habilitation center.

Immunization/Administration of Medication

Pharmacists immunizing or administering medication outside of the DHSS licensed premises must file a Notification of Intent to immunize and/or administer medication by prescription order with the Board and comply with rules 20 CSR 2220-6.040 and 20 CSR 2220-6.050.

Pharmacists immunizing by protocol are required to notify the authorizing protocol physician within seventy-two (72) hours after immunizing and notify the patient's primary care provider within fourteen (14) days after vaccination, if different. Additionally, pharmacists must notify the protocol physician within twenty-four (24) hours of an adverse event/reaction. Pending future Class-B rules, the Board has determined the required notifications may be documented in a common EMR that is accessible to both the pharmacist and physician. Proof of documentation/notification must be produced on inspection or as requested by the Board.

Licensees should review the Missouri Pharmacy Practice Guide for additional immunization/administration compliance information. The Board also has an Immunization/Administration Checklist available online at <http://pr.mo.gov/pharmacists-faq-compliance.asp#immunization>. Pharmacists immunizing or administering medication within the DHSS licensed hospital premises must comply with DHSS requirements.

Class-J Shared Services

Class-B pharmacies engaged in shared services with another Board licensed pharmacy must also have a Class-J pharmacy permit, in addition to their Class-B permit. A Class-J permit is required if a pharmacy will be using, or assisting another pharmacy with:

- Filling or refilling a prescription drug order, or
- Performing or assisting in the performing of any function associated with the dispensing process. This would include drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions for another pharmacy.

Pharmacies may participate in a Class-J shared services arrangement if both pharmacies:

- 1) Have the same owner or have a written contract outlining the shared services to be provided by, and the responsibilities of, each party participating in the contract; and
- 2) Maintain separate pharmacy licenses for each shared services location; and
- 3) Share a common electronic file that allows access to sufficient information necessary or required to fill/refill a prescription drug order. The pharmacies must share a record keeping system that provides real time, on-line access to shared services by both pharmacies.

Class-J pharmacies must also maintain a policy and procedure manual that describes/includes procedures for: (a) how the parties will comply with state/federal requirements (b) identifying the pharmacist responsible for dispensing and counseling, (c) tracking the prescription drug order during each step in the process, (d) maintaining adequate security to protect the confidentiality and integrity of patient information and (e) maintaining a quality assurance program for pharmacy services that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and resolve identified problems.

Once again, a Class-J permit is required for both pharmacies engaged in shared services. For example, a Class-B chemotherapy infusion pharmacy receives and fills a patient's prescription from a specialty mail order pharmacy (i.e., a manufacturer's indigent program). A Class-J permit would be required for both the Class-B chemotherapy infusion pharmacy and the specialty mail order pharmacy. Pharmacies may add a classification by filing a [Pharmacy Classification Change Application](#) with the applicable fee.

Transferring prescription information between Class-J pharmacies in a shared services arrangement that share a real-time, on-line database are not considered "prescription transfers" under, and are not subject to the requirements of, 20 CSR 2220-2.120. Other controlled substance laws may apply.

Record-Keeping

As a licensed pharmacy, Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. Licensees should review Missouri law and the Missouri Practice Guide for specific requirements. The Board has determined that Class-B pharmacies may maintain dispensing, distribution and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the records must be readily retrievable on inspection or if requested by the Board.⁵

Future Rules

The Board will be consulting with the Hospital Advisory Committee to develop future Class-B pharmacy rules. Interested parties should monitor the Board's website for meeting information; public comments are welcomed.

Questions

⁵ Controlled substance records must still be separately maintained/retrievable as required by state/federal law.

Questions regarding activities under DHSS' authority should be addressed to DHSS' Division of Hospital Licensure and Regulation at (573) . Questions regarding the Board's rules or requirements may be addressed to your Inspector or e-mailed to compliance@pr.mo.gov.