

**Meeting Notice
Missouri Board of Pharmacy
Hospital Advisory Committee
Conference Call**

**November 18, 2016, 1:00 p.m.
Missouri Division of 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 1:00 p.m. on November 18, 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.

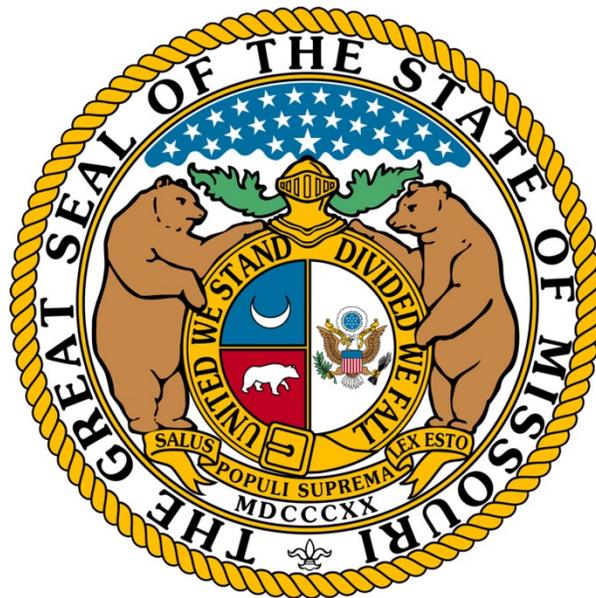
**TENTATIVE AGENDA
November 18, 2016 1:00 P.M.**

**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. Class-B Guidance Document
6. Review of Bd. Of Pharmacy Medication Therapy Services Rule
7. Proposed Class-B Rule Provisions
8. Selection/Discussion of Future Agenda Topics
9. Future Agenda Meeting/Schedules
10. Public Questions/Comments

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.

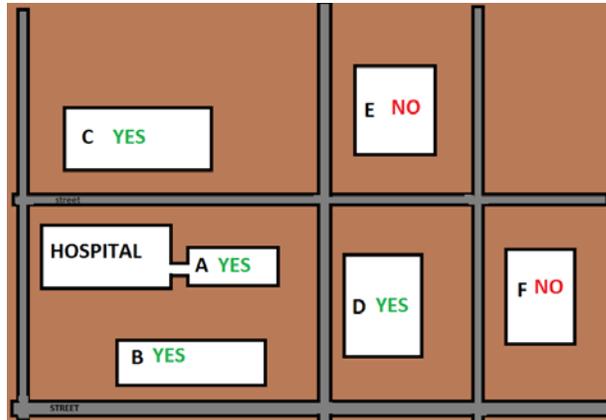
Class-B applications and related fees are available on the Board’s website. *Note: Applicants must apply for and hold any required classification for specialty pharmacy services regulated by the Board (e.g., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).*

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 (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. 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 | (6) Drug utilization review |
| (2) Obtaining patient history/information | (7) Pharmacy compliance audits/evaluations |
| (3) Reviewing patient records/medical reconciliation | (8) Peer review/peer consultations |
| (4) Patient assessment/evaluation | (9) Managing drug inventory, including purchasing and ordering |
| (5) Insurance billing and claims | |

- (10) Consulting with other health care professionals
- (11) Patient referrals
- (12) Medication therapy management/medication therapy services, and

- (13) Prescription order entry/review, provided a pharmacist can only accept a prescription on the premises of a Missouri licensed pharmacy [§ 338.095.5]

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 to have been “given to the patient for use/administration” offsite if medication administration is initiated, or the medication is loaded into a device, within the facility where a Class-B pharmacy is located but is continued or completed offsite intravenously or using an implanted device, port or catheter (e.g., intrathecal, 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.

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

Allowed Technician Activities

Generally, a Missouri pharmacy technician registration 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.

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

Questions

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.

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

20 CSR 2220-6.070 Certificate of Medication Therapeutic Plan Authority

PURPOSE: This rule establishes procedures for obtaining a certificate of medication therapeutic plan authority, as authorized by section 338.010, RSMo.

(1) A pharmacist shall obtain a certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient’s medication therapy or device usage. Pharmacists with a certificate of medication therapeutic authority shall enter into a written protocol with a Missouri-licensed physician that complies with the requirements of 20 CSR 2220-6.080, prior to performing medication therapy services.

(2) Applicants for certification shall hold an active Missouri pharmacist license. Applications shall be submitted on forms provided by the Missouri State Board of Pharmacy and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof the applicant—

(A) Holds a doctor of pharmacy (PharmD) degree earned from a school, accredited by the Accreditation Council for Pharmacy Education (ACPE); or

(B) Has successfully completed a post-graduate medication therapy certificate course or program accredited or granted by the APCE, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, or the American Pharmacists Association; or

(C) Holds a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators; or

(D) Has completed a post-graduate medication therapy certificate course that, at a minimum, included training in the following areas:

1. Assessing patient specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medication conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Improving patient care and outcomes through medication therapy services;

- 40 6. Evaluating treatment progress;
41 7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in
42 medication regimen reviews;
43 7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in
44 medication regimen reviews;
45 8. Medication reconciliation;
46 9. Drug utilization review;
47 10. Applicable state or federal law;
48 11. Formulating and documenting personal medication records;
49 12. Documenting clinical outcomes;
50 13. Interpreting, monitoring, ordering, and assessing patient test results; and
51 14. Patient education and counseling.

52 (3) Certificate Renewal. A certificate of medication therapeutic plan authority shall be
53 renewed biennially with the certificate holder's Missouri pharmacist license. For purposes
54 of renewal, six (6) of the continuing education hours required for renewing the certificate
55 holder's Missouri pharmacist license shall be earned in courses/programs related to
56 medication therapy management. The continuing education required by this rule shall be
57 governed by the rules of the Missouri State Board of Pharmacy governing pharmacist
58 continuing education.

59 (4) The Missouri State Board of Pharmacy may discipline or terminate a pharmacist's
60 certificate of medication therapeutic plan authority if the Missouri State Board of Pharmacy
61 determines that the pharmacist has violated the terms of a protocol, the requirements of
62 Chapter 338, RSMo, or rules of the board governing medication therapy services or any
63 other state or federal drug law.

64 *AUTHORITY: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011.* Original rule*
65 *filed Jan. 13, 2012, effective Aug. 30, 2012.*

66 **Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011;*
67 *338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

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69 **20 CSR 2220-6.080 Medication Therapy Services By Protocol**

70 *PURPOSE: This rule establishes procedures for the provision of medication therapy*
71 *services by protocol, as authorized by section 338.010, RSMo.*

72 (1) Except as otherwise provided herein, a pharmacist who holds a certificate of medication
73 therapeutic plan authority from the Missouri State Board of Pharmacy shall be authorized to
74 provide medication therapy services in Missouri if the pharmacist—

75 (A) Holds a current Missouri pharmacist license that is not under discipline with the
76 Missouri State Board of Pharmacy; and

77 (B) Has entered into a written protocol with a Missouri licensed physician that complies
78 with the requirements of this rule.

79 (2) General Requirements. A pharmacist may provide medication therapy services only with
80 current certification and as authorized by the protocol and the authorizing physician. A
81 pharmacist providing medication therapy services pursuant to this rule shall comply with
82 the following:

83 (A) Prior to providing medication therapy services, the pharmacist shall receive a
84 prescription order for a medication therapeutic plan from the authorizing physician for a
85 specific patient which authorizes the pharmacist to perform medication therapy services.
86 Except as otherwise provided in subsection (2)(B) of this rule, the prescription order for a
87 medication therapeutic plan shall be valid for no more than one (1) year and shall include:

- 88 1. The patient's name, address, and date of birth;
- 89 2. The date the prescription order for a medication therapeutic plan is issued;
- 90 3. The clinical indication for medication therapy services;
- 91 4. The length of time for providing medication therapy services, if less than one (1)
92 year; and
- 93 5. The authorizing physician's name and address;

94 (B) A prescription order for a medication therapeutic plan may be transmitted orally,
95 electronically, or in writing. If an oral prescription order for a medication therapeutic plan is
96 issued, all information required under subsection (2)(A) of this rule shall be documented by
97 the pharmacist and maintained in the patient's record in accordance with section (7) of this
98 rule;

99 (C) The pharmacist shall review relevant prescription records, patient profiles, patient
100 medical records, or other medical information to determine the services to be rendered; and

101 (D) In lieu of compliance with 20 CSR 2220-2.018, prescription orders for medication
102 therapy services shall comply with the provisions of this rule, provided the pharmacist shall
103 maintain the prescription order in the patient record required by section (7) of this rule and
104 shall document any change or alteration made to the prescription ordered based on contact
105 with the prescriber in the applicable patient record.

106 (3) Authorizing Physician Requirements.

107 (A) The authorizing physician shall be actively engaged in the practice of medicine in the
108 state of Missouri and shall hold a current and unrestricted Missouri physician license
109 pursuant to Chapter 334, RSMo.

110 (B) The authorizing physician shall be responsible for the oversight of the medication
111 therapy services provided by the pharmacist that are authorized by protocol. The
112 authorizing physician shall also consider the level of skill, education, training, and
113 competence of the pharmacist and ensure that the activities authorized by the protocol are
114 consistent with the pharmacist's level of skill, education, training, and competence.

115 (C) The written protocol shall be reviewed and signed by the pharmacist and the
116 authorizing physician at least annually and revised as needed. The authorizing physician
117 and pharmacist shall document the date of the annual review on the written protocol.

118 (D) The authorizing physician shall review the pharmacist's medication therapy service
119 activities regularly, but not less than once every three (3) months. If the pharmacist is
120 providing medication therapy services for, or on behalf of, a health care entity, the review
121 requirements shall be satisfied if the pharmacist's work and services are reviewed every
122 three (3) months by a clinical care committee, pharmacy and therapeutics committee, or a
123 reviewing body/committee of the health care entity that includes a Missouri-licensed
124 physician. The review required by this subsection may be accomplished in person or by
125 electronic means.

126 (E) The practice location of the authorizing physician shall be no further than fifty (50)
127 miles by road from the pharmacist identified in the written protocol.

128 (F) An authorizing physician shall notify the Missouri State Board of Registration for the
129 Healing Arts of a written protocol for medication therapy services entered with a pharmacist
130 at each renewal of the authorizing physician's license.

131 (4) Protocol Requirements.

132 (A) The medication therapy services performed by a pharmacist pursuant to the protocol
133 shall be within the authorizing physician's scope of practice and within the skill, education,
134 training, and competence of both the authorizing physician and the pharmacist.

135 (B) The written protocol between the authorizing physician and pharmacist shall, at a
136 minimum, include the following:

- 137 1. The identity and signatures of the authorizing physician and pharmacist;
- 138 2. The effective dates of the protocol;
- 139 3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug
140 categories included in the written protocol and the type of medication therapy services
141 allowed in each case;
- 142 4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is
143 to follow when conducting medication therapy services;
- 144 5. Procedures for documenting medication therapy decisions made by the pharmacist
145 and a plan for communication, feedback, and reporting to the authorizing physician
146 concerning specific decisions made;
- 147 6. A mechanism and procedure that allows the authorizing physician to override,
148 rescind, modify, or otherwise amend the protocol. All modifications or amendments to the
149 protocol shall be documented in writing, signed, and dated by all involved parties prior to
150 the implementation of such modification or amendment. The protocol may be immediately
151 rescinded by the authorizing physician or the pharmacist with or without cause, provided
152 the rescission is documented in writing. If any conflict arises regarding the professional
153 judgment of the pharmacist and physician with regard to the subject of the medication
154 therapy services, the physician has ultimate authority;

155 7. A statement that the pharmacist shall not delegate the responsibility of medication
156 therapy services to another person;

157 8. A description of any authority granted to the pharmacist to administer any drug or
158 medication including the identification of any such drug, medication, or device;

159 9. A description of drug therapy related patient assessment procedures or testing that
160 may be ordered or performed by the pharmacist, including any authority to order or perform
161 routine or other laboratory testing;

162 10. Provisions for allowing the pharmacist to access the patient's medical records for
163 purposes of providing medication therapy services;

164 11. A provision for providing the authorizing physician access to patient records for
165 medication therapy services provided by the pharmacist for patients of the authorizing
166 physician;

167 12. Provisions establishing a course of action the pharmacist is authorized to follow to
168 address emergency situations, including, but not limited to, anaphylactic or other adverse
169 medication reactions, adverse needle sticks, or other adverse events;

170 13. Criteria for timely communication from the authorizing physician to the pharmacist
171 and from the pharmacist to the authorizing physician, not inconsistent with the provisions of
172 this rule;

173 14. The notification requirements required by section (5) of this rule; and

174 15. The method for reviewing the pharmacist's medication therapy work or services by
175 the authorizing physician, as required by subsection (3)(D) of this rule.

176 (C) The written protocol shall include a description of medication therapy services the
177 pharmacist is authorized to render or provide. Such services may include:

178 1. Assessing patient-specific data and issues;

179 2. Establishing medication therapeutic goals or medication related action plans for
180 identified medical conditions and medication related concerns;

181 3. Assessing and addressing adverse reactions and adverse drug events;

182 4. Modifying and monitoring medication regimens;

183 5. Evaluating treatment progress;

184 6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in
185 medication regimen reviews;

186 7. Medication reconciliation;

187 8. Drug utilization review;

188 9. Formulating and documenting personal medication records;

189 10. Documenting clinical outcomes;

190 11. Interpreting, monitoring, and assessing patient test results;

191 12. Initiation of drug therapy, as authorized by protocol; and

192 13. Patient education and counseling.

193 (D) The protocol required by this section shall be signed and dated by the authorizing
194 physician and the pharmacist. If the protocol includes multiple authorizing physicians or
195 participating pharmacists, a separate protocol shall not be required for each physician or
196 pharmacist if all authorizing physicians and pharmacists have signed and dated a statement
197 agreeing to be governed by the terms of the written protocol.

198 (E) Any revisions, modifications, or amendments to the protocol must be in writing. The
199 authorizing physician shall promptly notify the pharmacist of any such revision,
200 modification, or amendment and shall maintain documentation of the notification, including
201 the date such notification was made. The authorizing physician may delegate the
202 notification requirements of this subsection to an authorized designee, provided the
203 physician shall be ultimately responsible for compliance with the notification requirements.

204 (F) A pharmacist shall not be authorized to adjust, change, or modify any controlled
205 substance prescribed for a patient, except as authorized by state or federal law.

206 (G) The protocol shall be maintained by the authorizing physician and the pharmacist for
207 a minimum of eight (8) years after termination of the protocol. The protocol may be
208 maintained electronically.

209 (H) A protocol shall automatically and immediately terminate if the pharmacist ceases to
210 maintain an active Missouri pharmacist license, the authorizing physician is deceased, or if
211 the authorizing physician fails to maintain an active, unrestricted Missouri physician
212 license.

213 (I) Pharmacy Residents. If specifically authorized by the protocol, a pharmacy resident
214 shall be authorized to perform medication therapy services under the written protocol of a
215 Missouri pharmacist in lieu of an individual protocol, if—

216 1. The resident holds a certificate of medication therapeutic plan authority from the
217 Missouri State Board of Pharmacy;

218 2. The resident is enrolled in a residency training program accredited by the American
219 Society of Health-System Pharmacists or a residency training program with a valid
220 application for accreditation pending with the American Society of Health-System
221 Pharmacists; and

222 3. The resident is providing medication therapy services under the supervision of a
223 Missouri pharmacist certified by the Missouri State Board of Pharmacy to perform
224 medication therapy services.

225 (J) The provisions of subsection (4)(I) shall only apply to medication therapy services
226 provided by a pharmacist as part of his/her residency training.

227 (5) Notification Requirements. A pharmacist shall comply with the following notification
228 requirements:

229 (A) Within twenty-four (24) hours after learning of an anaphylactic or other adverse
230 medication reaction, adverse needle stick, or other adverse event experienced by a patient,
231 the pharmacist shall notify the patient's authorizing physician or an authorized designee of
232 the authorizing physician;

233 (B) The pharmacist shall notify the authorizing physician or an authorized designee of the
234 authorizing physician in the written protocol of any modification of therapy, within twenty-
235 four (24) hours, provided the protocol may include more stringent notification requirements;

236 (C) A pharmacist shall be deemed in compliance with the notification requirements of this
237 rule if the pharmacist is providing medication therapy services for, or on behalf of, a health
238 care entity, as defined by this rule, and documentation of the notifications required by this
239 section is recorded in a patient medical record that is required to be maintained by the health
240 care entity pursuant to state or federal law; and

241 (D) Notifications required by this section shall be in writing unless otherwise authorized
242 by the authorizing physician.

243 (6) Modifying Drug Therapy.

244 (A) A pharmacist may be authorized by protocol to modify a patient's non-controlled
245 substance medication therapy, subject to the following:

246 1. If the pharmacist modifies medication therapy and a medication or device is to be
247 dispensed, the pharmacist shall create a prescription for the medication or device modified
248 under the authorizing physician's name. Such prescription may be dispensed by a licensed
249 pharmacy and shall be maintained in the prescription records of the dispensing pharmacy as
250 provided by the rules of the Missouri State Board of Pharmacy; and

251 2. If the pharmacist modifies medication therapy or a device, the pharmacist shall
252 document such modification according to section (7) of this rule. Pharmacists providing
253 medication therapy services for patients of a health care entity shall be deemed in
254 compliance with the provisions of this subsection if the modification is documented in a
255 patient medical record that the health care entity is required to maintain under state or
256 federal law.

257 (B) The pharmacist shall not modify any controlled substance prescription. A prescription
258 from the authorizing physician shall be required to modify a controlled substance.

259 (C) For purposes of 20 CSR 2220-6.060, 20 CSR 2220-6.070, and 20 CSR 2220-6.080,
260 modification of medication therapy shall include selecting a new, different, or additional
261 medication or device, discontinuing a current medication or device, or selecting a new,
262 different, or additional strength, dose, dosage form, dosage schedule, or route of
263 administration for a current medication or device, and implementing such selection(s).
264 Medication therapy services shall not include the sole act of dispensing a drug or device
265 pursuant to a valid prescription for the product or generic substitutions made pursuant to
266 section 338.056, RSMo.

267 (7) Record Keeping.

268 (A) A pharmacist shall document and maintain an adequate patient record of medication
269 therapy services provided to each patient. The records may be maintained in electronic
270 format provided the records are capable of being printed for review by the Missouri State
271 Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy. An
272 adequate and complete patient record shall include documentation of the following:

273 1. The identification of the patient, including, name, birthdate, address, and telephone
274 number;

275 2. The date(s) of any patient visit or consultation, including the reason for any such
276 visit/consultation;

277 3. Any pertinent assessments, observations, or findings;

278 4. Any diagnostic testing recommended or performed;

279 5. The name of any medication or device modified and the strength, dose, dosage
280 schedule, dosage form, and route of administration of any medication modified or
281 administered;

282 6. Referrals to the authorizing physician;

283 7. Referrals for emergency care;

284 8. Any contact with the authorizing physician concerning the patient's treatment or
285 medication therapy services plan;

286 9. Any informed consent for procedures, medications, or devices; and

287 10. Any consultation with any other treatment provider for the patient and the results of
288 such consultation.

289 (B) Pharmacist Record Retention. Except as otherwise provided herein, records required
290 to be maintained by a pharmacist pursuant to this rule shall be maintained securely and
291 confidentially for a minimum of seven (7) years after termination of the protocol unless
292 more stringent requirements are established for record keeping under state or federal law.
293 All records required to be maintained by the pharmacist by this rule shall be maintained by
294 the pharmacist at an address that shall be identified in the written protocol.

295 (C) Physician Record Retention. Except as otherwise provided herein, records required to
296 be maintained by the authorizing physician pursuant to this rule shall be maintained
297 securely and confidentially for a minimum of seven (7) years after termination of the
298 protocol unless more stringent requirements are established for record keeping pursuant to
299 state or federal law.

300 (8) Production of Records. Records maintained at a pharmacy must be produced during an
301 inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board
302 of Registration for the Healing Arts, or their authorized representatives, as requested by the
303 respective board or the board's designee. Records not maintained at a pharmacy shall be
304 produced within three (3) business days after a request from the Missouri State Board of
305 Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized
306 representative. Failure to maintain or produce records as provided by this rule shall
307 constitute grounds for discipline.

308 (9) Nothing in this rule shall be construed to permit medical diagnosis of any condition by a
309 pharmacist or the independent issuing of a prescription by a pharmacist.

310 (10) A pharmacist shall not violate or practice in a manner inconsistent with the provisions
311 of this rule or a written protocol. A pharmacist's failure to abide by the requirements of this
312 rule or the provisions of a written protocol shall be subject to disciplinary action pursuant to
313 the provisions of Chapter 338, RSMo.

314 (11) The requirements of this rule shall not apply to the administration of vaccines pursuant
315 to protocol as governed by 20 CSR 2220-6.050 or the administration of medication by
316 protocol as governed by 20 CSR 2220-6.040.

317 (12) The Missouri State Board of Registration for the Healing Arts and the Missouri State
318 Board of Pharmacy separately retain the right and duty to discipline their respective
319 licensees for violations of any state or federal statutes, rules, or regulations regardless of the
320 licensee's participation in a protocol agreement.

321 (13) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026
322 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the
323 jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of
324 Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334,
325 RSMo.

326 *AUTHORITY: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011.* Original rule*
327 *filed Jan. 13, 2012, effective Aug. 30, 2012.*

328 **Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011;*
329 *338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*
330

PROPOSED CLASS-B RULE

- Facility requirements
- Use of automated dispensing systems
- Maintenance/Supervision of drug inventory outside of the pharmacy
- Medication labeling
- Access by nursing/hospital staff
- Medication dispensing/access after pharmacy hours