REVISED MEETING NOTICE

Missouri Board of Pharmacy
Hospital Advisory Committee Meeting
CONFERENCE CALL

January 13, 2017
10:00 a.m.

***Due to anticipated inclement weather, the Hospital Advisory Committee will be meeting on January 13, 2017 via conference call.***

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy’s Hospital Advisory Committee is authorized to close meetings, records and votes pursuant to Section 610.021(1).

The Committee 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 by participating in the conference call, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 10:00 a.m. on January 13, 2017.

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
January 13, 2017
10:00 a.m.

Missouri Board of Pharmacy
Hospital Advisory Committee Meeting
CONFERENCE CALL

January 13, 2017
10:00 a.m.

***Due to anticipated inclement weather, the Hospital Advisory Committee will be meeting on January 13, 2017 via conference call.***

1. Welcome & Introductions
2. Board Updates
3. Department of Health Updates
4. Approval of Minutes
5. Review of Class-B Draft Guidance
6. Class-B Proposed Rule Topics
8. Review of Missouri Medication Therapy Services Requirements, including, § 338.010, RSMo, § 338.165, RSMo & 20 CSR 2220-6.080
9. Discussion of Missouri Society of Health-System Pharmacists (MSHP) Practice Advancement Initiative/Medication Therapy Services Advanced Pharmacy Practice Meeting
10. Remote Supervision of Pharmacy Technicians
11. Joint Commission Compounding Accreditation Program
12. Future Agenda Topics
13. Future Agenda Meeting/Schedules
14. Public Questions/Comments
15. Adjournment
OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

October 21, 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
James Gray, R.Ph., Member
Colby Grove, R.Ph., Member
Kevin Kinkade, R.Ph., Member
Greg Teale, R.Ph., Member

Committee Members Absent
Daniel Good, R.Ph., Member (participated via conference call)
Neil Schmidt, R.Ph., Member

Staff Present
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector
Alicia Edmonson, Compliance Coordinator

Others Present
Barbara Bilek, Board Member
David Wolfrath, MSHP

Chairman McClary opened the meeting at 10:05 a.m. and attendees were introduced.

Agenda Item # 2 (Approval of Minutes): The minutes included in the agenda were presented for approval. A motion was made by Kevin Kinkade, seconded by Colby Grove, to approve the July 15, 2016, minutes. The motion passed 4:0:0:2 with roll call vote as follows:

<table>
<thead>
<tr>
<th>Member</th>
<th>Vote</th>
</tr>
</thead>
<tbody>
<tr>
<td>James Gray</td>
<td>yes</td>
</tr>
<tr>
<td>Greg Teale</td>
<td>yes</td>
</tr>
<tr>
<td>Colby Grove</td>
<td>yes</td>
</tr>
<tr>
<td>Daniel Good</td>
<td>absent</td>
</tr>
<tr>
<td>Neil Schmidt</td>
<td>absent</td>
</tr>
<tr>
<td>Kevin Kinkade</td>
<td>yes</td>
</tr>
</tbody>
</table>

A motion was made by Kevin Kinkade, seconded by Colby Grove, to approve the August 26, 2016, minutes. The motion passed 4:0:0:2 with roll call vote as follows:

<table>
<thead>
<tr>
<th>Member</th>
<th>Vote</th>
</tr>
</thead>
<tbody>
<tr>
<td>James Gray</td>
<td>yes</td>
</tr>
<tr>
<td>Greg Teale</td>
<td>yes</td>
</tr>
<tr>
<td>Colby Grove</td>
<td>yes</td>
</tr>
<tr>
<td>Daniel Good</td>
<td>absent</td>
</tr>
<tr>
<td>Neil Schmidt</td>
<td>absent</td>
</tr>
<tr>
<td>Kevin Kinkade</td>
<td>yes</td>
</tr>
</tbody>
</table>
**Agenda Item # 3 (Board Updates):** Tom Glenski provided information on the upcoming October 2016 meeting. Mr. Glenski noted the Class-B guidance document will be reviewed by the Board in October as well as rule 20 CSR 2220-6.055 (Non-Dispensing Activities). Chairman McClary asked if the Committee wanted to make an official comment on 20 CSR 2220-6.055. Committee discussion was held. James Gray noted the rule should allow pharmacists to provide patient training on medication related activities such as preparing drugs for administration or drawing an insulin syringe.

Further Committee discussion was held on creating a framework to allow pharmacists to engage in non-traditional dispensing outside of the pharmacy. Greg Teale commented 20 CSR 2220-6.055 may need to be revised if pharmacists are granted provided status. Committee consensus not to make an official recommendation on 20 CSR 2220-6.055 at this time but to monitor future developments.

**Agenda Item # 4 (Dept. of Health Updates):** Tom Glenski and Katie DeBold reported the Board will be providing sterile compounding training for DHSS surveyors.

Committee Member Daniel Good joined the conference call at 11:09 A.M.

**Agenda Item # 5 (Class-B Rule Topics):** Tom Glenski presented the draft list of previously suggested Class-B rule topics. Committee discussion was held. Committee members suggested including an exemption in the draft rule that would allow medication to be returned from a clinic for destruction; Committee members further suggested including provisions that would address medication therapy services, automated dispensing cabinets and long-term care dispensing.

Additional discussion was held regarding the drug distributor chart in the draft Class-B practice guide. Committee members expressed the chart may still be confusing and may need to address additional distribution scenarios. Committee consensus to revise the chart for future review.

**Agenda Item # 6 (Review of Applicability of Board’s Medication Therapy Services Rules):** Bert McClary indicated confusion still exists regarding the applicability of the Board’s medication therapy (MT) services rule to MT services provided in clinics located within a hospital. Mr. McClary asked if the Board’s rule would apply if a prescription/discontinuance order is subsequently communicated by a hospital pharmacist to a pharmacy under the Board’s jurisdiction. Mr. McClary suggested asking for additional Board clarification and addressing this issue in a future hospital guidance. Mr. McClary asked members to review 20 CSR 2220-6.080 and bring any suggested changes/comments to the next meeting.

Executive Director Kimberly Grinston joined the meeting at 11:45 A.M.
The following additional discussion was held on Agenda Item # 6:

- Mr. McClary asked to discuss authorization of medication therapy services by mid-level practitioners at a future meeting. Greg Teale asked if the law could authorize collaborative agreements with mid-level practitioners; Tom Glenski indicated a statutory change would be required. Mr. McClary suggested MT protocols could be structured to allow initiation of MT services as approved by the Executive Committee with the mid-level practitioner simply confirming what has already been ordered. Committee members asked if the protocol physician could allow the mid-level practitioner to initiate the protocol. Tom Glenski again noted statutory changes may be necessary.

**Agenda Item # 3 (Board Updates- Cont’d):** Bert McClary asked Executive Director Grinston to provide updates on the Pharmacy Technician Working Group. Kimberly Grinston reported the Working Group has preliminarily suggested establishing an advanced technician class that would be allowed to perform advanced technician duties and required to be certified or complete additional education/training.

James Gray noted there may be legal issues with a certification only approach and noted some workers in protected groups may have issues with passing the certification exam. Bert McClary noted that additional standards/training would need to be in place if technicians are to be recognized as a paraprofessional class. James Gray agreed but noted the question is how the additional requirements would be implemented. Mr. McClary noted the Board’s jurisdiction over technicians working in a DHSS licensed hospital is still unclear. Additional Committee discussion was held.

Kevin Kinkade noted there may be unique challenges for smaller or rural hospitals and indicated that finding certified technicians with the right expertise may be difficult. Greg Teale noted remote technician supervision may be beneficial for smaller or rural hospitals; Kevin Kinkade agreed remote supervision would aide hospitals that cannot afford a full-time pharmacist. Daniel Good suggested it would be better for the industry to address technician supervision/training before a catastrophic event happens that may require legislative intervention. James Gray and Barbara Bilek commented the technician issue is an important component of advancing patient safety and quality.

**Agenda Item #7 (Automated Dispensing Cabinets):** Tom Glenski reported he met with Greg Teale to gather additional information on the use of automated dispensing cabinets by Class-B pharmacies. Mr. Glenski suggested many of the issues could possibly be addressed in a Class-N or Class-O pharmacy rule. Mr. Glenski noted the current automated dispensing rule does not adequately accommodate the situations discussed. Committee discussion was held.

Bert McClary suggested the Board’s automated dispensing rule should allow a pharmacy to place an automated dispensing system at a healthcare facility that is owned/operated by a hospital and oversee dispensing. Tom Glenski suggested drafting
a new Class-P rule. Greg Teale commented that the future rule should allow medication in an automated dispensing system to remain a part of the pharmacy system. Committee consensus to consider a draft rule. Mr. McClary noted the DEA may need to be consulted on controlled substance registration requirements.

**Agenda Item #8 (Review of Joint Board/DHSS Rule Requirements):** Bert McClary asked for clarification on what rules have to be jointly promulgated under § 338.165.3, RSMo. Kimberly Grinston indicated the statute appears to provide joint promulgation is allowed but not required. Mr. McClary asked if it would be appropriate for the Board to officially ask DHSS to finalize the hospital pharmacy rules. Committee discussion was held. Mr. McClary expressed he wanted to maintain a strong collaborative relationship with DHSS and did not want to create additional work for the Department. Committee consensus to take no further action at this time but to discuss the applicability of § 338.165.3 at a future meeting.

**Agenda Items # 11 and 12 (Future Agenda Topics/Dates):** Bert McClary asked Committee members to prioritize future discussion items. Committee discussion was held. Committee consensus to prioritize the MTS discussion, the Class-B guidance document and a potential Class-N or Class-P rule to address automated dispensing. Committee consensus to hold the next in-person meeting on January 13, 2017, in Jefferson City.

**ADJOURNMENT**
A motion was made by Greg Teale to adjourn the meeting, Bert McClary adjourned the meeting by consensus at approximately 3:00 p.m.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
The Missouri Hospital Advisory Committee met in open session via conference call 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
Colby Grove, R.Ph., Member
Kevin Kinkade, R.Ph., Member
Neil Schmidt, R.Ph., <e,ner

**Committee Members Absent**
James Gray, R.Ph., Member
Greg Teale, R.Ph., Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector

**Others Present**
Julie Creach, Missouri Dept. of Health and Senior Services
Sarah Willson, Missouri Hospital Association
David Wolfrath, MSHP

Chairman McClary opened the meeting at 1:30 p.m. and roll-call was taken.

**Agenda Item # 2 (Approval of Minutes):** Kimberly Grinston reported minutes were not available at this time.

**Agenda Item # 3 (Board Updates):** Kimberly Grinston reported the Board will be reviewing the draft immunization by protocol rule and the administration by medical prescription order rule at the January 2017 meeting along with several Class-B related issues. Bert McClary inquired about the Pharmacy Technician Working Group meeting dates; Ms. Grinston indicated a final date has not been confirmed.

Mr. McClary asked if the Board will be following the previously published rule review calendar and noted Committee members might be interested in the Board’s pharmacy technician and pharmacy permit rules. Mr. McClary further suggested coordinating the
Committee’s discussion on technician issues with the Board’s review of the general technician rule. Mr. McClary also noted the medication therapy services (MTS) rules are scheduled for review in April 2017 and asked if the Board would be looking at a specific proposal. Ms. Grinston indicated the Board will be doing a general review of the rule and provided that no specific rule changes have been drafted for Board review.

**Agenda Item # 4 (DHSS Updates):** Julie Creach did not have additional updates from DHSS but thanked the Board for providing sterile compounding training for DHSS surveyors. Ms. Creach indicated the training was informative and received positive feedback from attendees.

**Agenda Item # 5 (Review of Class-B Guidance Document):** Kimberly Grinston presented the draft Class-B guidance document and noted the draft has not been finally approved by the Board. Committee discussion was held regarding the proposed language on medication dispensed for offsite use/administration. David Wolfrath commented the language may not accommodate products like the Neulasta Onpro kit and noted administration may not begin with the kit until more than twenty-four (24) hours after it is applied.

Additional Committee discussion was held. Committee consensus to revise page 10 of the draft guidance to provide:

3) The medication/prescription container is not “given to the patient for use/administration” offsite. The Board will not consider medication to have been given to the patient for offsite use/administration if medication administration is initiated onsite but continued offsite by a parenteral infusion method, including, but not limited to, a subcutaneous, intrathecal or intravenous method or via an implanted device, port or catheter.”

Chief Inspector Glenski commented the final document will be for guidance purposes only. Mr. Glenski expressed it would be difficult to address all possible scenarios in a guidance document or rule and noted the Board would still have enforcement discretion.

**Agenda Item # 7 (Proposed Class-B Rule Provisions):** Kimberly Grinston reported the following topics were previously suggested by the Committee for a future 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 and medication dispensing/access after pharmacy hours. Bert McClary indicated the summary appeared to be accurate. Kevin Kinkade asked if the future rule should address drug security or technician supervision. Bert McClary indicated security issues would likely be addressed under other topics already listed. Mr. McClary further suggested holding the pharmacy technician issues until the conclusion of the Pharmacy Technician Working Group’s recommendations. Committee consensus to hold the pharmacy technician discussion items as suggested.
Mr. McClary asked if the rule should address pharmacist dispensing from the emergency department (ED). Sarah Willson questioned why a pharmacist would be restricted from dispensing from the ED and noted a nurse is currently authorized to dispense in a limited supply. Mr. McClary indicated medication is being sent home with the patient and noted DHSS rules currently prohibit a pharmacist from ED dispensing. Tom Glenski commented DHSS rules specifically indicate the dispensing party must be someone “other than a pharmacist.”

Mr. McClary asked if DHSS’ rule should be changed to allow a pharmacist to participate in the ED dispensing process when necessary. Mr. McClary commented this situation may be rare but noted the draft DHSS pharmacy rules contain language that would allow the hospital to send medication home with a patient if there is a significant public health issue. Mr. McClary noted examples would include instances where the medication is needed to treat or prevent a sexually-transmitted or other communicable disease and there are indications the patient may not otherwise have the medication filled. Additional Committee discussion was held. Kimberly Grinston noted the dispensing issue may be addressed when discussing medication dispensing/after-hours pharmacy access. Committee consensus to review the ED dispensing issue during future rule discussions.

BOARD VICE-PRESIDENT CHRISTIAN TADRUS JOINED THE CALL AT 1:55 P.M.

Agenda Item # 6 (Medication Therapeutic Services (MTS) Rule): Bert McClary indicated the Committee would not be able to discuss the rule on the call because of time. However, Mr. McClary asked to review the MTS rule at the Committee’s January meeting.

Mr. McClary indicated a primary concern with the rule is clarifying when the rule is applicable. Mr. McClary noted the current interpretation is that the rule does not apply within the licensed premises of a hospital but would apply when medication will be dispensed outside of the hospital. Mr. McClary further suggested that the rule address/clarify the definitions of a health care entity, prescription order, therapeutic plan and a protocol. Mr. McClary noted some of these terms are defined differently in the administration rule and suggested coordinating the definitions with both the administration rule and section 338.095, RSMo.

Mr. McClary asked Committee members to bring MTS rule discussion items/potential amendment suggestions to the January 2017 meeting.

Agenda Items # 8 & 9 (Future Agenda Topics/Dates): Mr. McClary suggested prioritizing the MTS and pharmacy technician discussions at the January meeting. Committee consensus to prioritize the items as suggested; Further Committee consensus to host an in-person meeting in Jefferson City on January 13, 2017 and a conference call on February 8, 2017.
ADJOURNMENT
By motion of Neil Schmidt, Chairman McClary adjourned the meeting by consensus at approximately 2:26 p.m.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
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
2. Obtaining patient history/information
3. Reviewing patient records/medical reconciliation
4. Patient assessment/evaluation
5. Insurance billing and claims
6. Drug utilization review
7. Pharmacy compliance audits/evaluations
8. Peer review/peer consultations
9. Managing drug inventory, including purchasing and ordering
(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, inventoring 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. Licenses distributing non-patient specific medication may also be required to register with the FDA as a section 503(b) drug outsourcer. Licensees should consult with legal counsel to ensure compliance with state and federal law.

**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].

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

---

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

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], and

3) The medication/prescription container is not “given to the patient for use/administration” offsite. The Board will not consider medication to have been given to the patient for offsite use/administration if medication administration is initiated onsite but continued offsite by a parenteral infusion method, including, but not limited to, a subcutaneous, intrathecal or intravenous method or via an implanted device, port, or catheter. The Board will not consider medication to have been given to the patient for offsite use/administration if medication administration is initiated onsite but continued offsite via a locked, pre-programmed external or implanted medication delivery device that does not require programming by the patient or caregiver.

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.

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

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. 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).

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

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

residential care facility, assisted living facility, intermediate care facility, skilled nursing facility or a habilitation center.
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

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

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.
TO: Hospital Advisory Committee Members
FROM: Kimberly Grinston,
Executive Director
RE: Future Class-B Rule/Class-N Rule
DATE: January 5, 2017

The office is in the process of drafting a potential Class-B rule based on the Committee’s previous suggestions. At the same time, staff will be presenting a concept draft to the Board at its January meeting for a future Class-N Automated Dispensing Systems (Health Care Facilities) rule.

Staff is asking for any suggestions/comments on the Class-N concept draft which would address several of the items suggested for the Class-B rule. The Class-N draft is in its very early stages and is not an official staff recommendation. Instead, staff is asking for Committee input on the general approach and will finalize the draft based on the Board’s direction in January.

In regards to the Class-B rule, staff has the following specific questions for the Committee:

1. Facility Requirements:
   a. What facility requirements need to be modified/accommodated?

2. Medication Labeling:
   a. What labeling requirements should (or should not) apply?

3. Pharmacy Access by Nursing/Hospital Staff: Does this need to be addressed if the Class-N rule allows pharmacies to store medication outside of the pharmacy? If yes:
   a. Should pharmacy access be limited to licensed healthcare professionals?
   b. Should medication access be restricted (e.g., controlleds vs. non-controlleds)?
   c. Should pharmacist review/approval be required for the first dose?
   d. Should the rule require a medication review or an inventory reconciliation?

4. Medication Dispensing/Access After Pharmacy Hours
   a. Should after-hours access be limited to licensed healthcare practitioners?
   b. Should medication access be restricted (e.g., controlleds vs. non-controlleds)?
c. Should after-hours access be limited to refills only?
d. What type of pharmacist review should be required, if any?

5. Medication Therapy Services
   a. What specific issues need to be addressed?

6. Long-Term Care Facilities
   a. What specific long-term care issues need to be addressed?
TO:        Hospital Advisory Committee Members
FROM:      Kimberly Grinston,
           Executive Director
RE:        Future Class-B Rule
DATE:      January 5, 2017

The office is in the process of drafting a potential Class-B rule based on the Committee’s previous suggestions. At the same time, staff will be presenting a concept draft to the Board at its January meeting for a future Class-N Automated Dispensing Systems (Health Care Facilities) rule.

Staff has the following specific questions on the Class-B rule:

1. Facility Requirements:
   a. What facility requirements need to be modified/accommodated in the rule?

2. Medication Labeling:
   a. What labeling requirements should (or should not) apply?

3. Pharmacy Access by Nursing/Hospital Staff: Does this need to be addressed if the Class-N rule allows pharmacies to store medication outside of the pharmacy? If yes:
   a. Should pharmacy access be limited to licensed healthcare professionals?
   b. Should medication access be restricted (e.g., controlleds vs. non-controlleds)?
   c. Should pharmacist review/approval be required for the first dose?
   d. Should the rule require a medication review or an inventory reconciliation?

4. Medication Dispensing/Access After Pharmacy Hours
   a. Should after-hours access be limited to licensed healthcare practitioners?
   b. Should medication access be restricted (e.g., controlleds vs. non-controlleds)?
   c. Should after-hours access be limited to refills only?
   d. What type of pharmacist review should be required, if any?

5. Medication Therapy Services
   a. What specific issues need to be addressed?

6. Long-Term Care Facilities
   a. What specific long-term care issues need to be addressed?
TO: Hospital Advisory Committee Members

FROM: Kimberly Grinston,  
Executive Director

RE: Future Class-N Rule

DATE: January 5, 2017

At the November meeting, the Committee asked to discuss a potential rule that would allow/enhance use of automated dispensing systems. Staff will be presenting a concept draft to the Board at its January meeting for a future Class-N Automated Dispensing Systems (Health Care Facilities) rule.

Staff is asking for any suggestions/comments on the Class-N concept draft. The draft is in its very early stages and is not an official staff recommendation. Instead, staff is asking for Committee input on the general approach and will finalize the draft based on the Board’s direction in January.
This draft has not been approved by the Board and is not being proposed or suggested by Board staff. The included language is intended solely for discussion purposes and to assist the Board in developing a future Class-N rule.

20 CSR 2220-2.850 Class-N Automated Dispensing Systems (Health Care Facilities)

PURPOSE: This rule establishes guidelines for the use of automated dispensing and storage systems.

(1) Definitions.
   (A) Automated Dispensing System: A mechanical/automated system that is used to store, package and dispense medication for patient use or administration. An automated dispensing system does not include a mechanical/automated system used for compounding or administering medication or an automated filling system governed by 20 CSR 2220-2.950.
   (B) Dispense/Dispensing - The provision of medication by a Missouri licensed pharmacy or pharmacist pursuant to a legally valid prescription or medication order for the ultimate user.
   (C) “Electronic Verification System” - An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated dispensing system.
   (D) Health Care Facility-
      1. A location other than a pharmacy or a licensed health care facility where healthcare services are provided to patients by a Missouri licensed healthcare practitioner at the same location; or
      2. An entity or organization that is licensed or certified by the state or federal government as a hospital, 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 as defined by Chapter 630, RSMo.
   (E) Licensed Health Care Practitioner- A Missouri licensed healthcare practitioner authorized to prescribe or a Missouri licensed dentist, licensed practical nurse, optometrist, pharmacist, physician, physician assistant, podiatrist, registered nurse, surgeon or veterinarian.
   (F) “Manufacturer Unit of Use Package” - A drug dispensed in the manufacturer’s original and sealed packaging, or in the original and sealed packaging of a repackager registered with the United States Food and Drug Administration (FDA), without additional manipulation or preparation by the pharmacy except for application of the required pharmacy label.
   (G) Medication Order: A medication order as defined by § 338.165.1(5), RSMo.
(2) Authorized Activities. A Class-N automated dispensing system may be operated in a healthcare facility to dispense medication that will be provided or administered to a patient by a licensed healthcare practitioner at or within the healthcare facility. A Class-N automated dispensing system shall not be used to dispense medication that will be used by or administered to the patient outside of the healthcare facility. Medication shall not be deemed to have been dispensed for offsite patient use/administration if administration is initiated onsite of the healthcare facility by a licensed healthcare professional but continued offsite by a parenteral infusion method, including, but not limited to, a subcutaneous, intrathecal or intravenous method or via an implanted device, port, catheter or pump.

(3) Licensure. Applicants for a Class-N pharmacy permit shall submit an application in a form and manner approved by the Board along with the required application fee. The application must identify the address where the automated dispensing system will be operated and shall identify a supervising Missouri licensed pharmacy that is responsible for managing system operations. [Some states mandate that only a licensed pharmacy can apply for an automated dispensing license. Should this be included in Missouri’s rule?]

(A) A Class-N automated dispensing system must successfully pass a Board inspection prior to issuance of the permit. Once approved, a Class-N permit will be issued for the specific location inspected by the Board. A Change of Location application must be filed with the board if the system is moved to a different facility or address. Operation of the system must cease until the Change of Location application has been approved by the board and a new pharmacy permit issued.

(B) A Class-N permit may only be used to perform authorized Class-N pharmacy services. An additional pharmacy permit is required to provide other pharmacy services authorized by Chapter 338, RSMo.

(C) Remodeling plans for a Class-N system must be submitted to the Board in advance for review and approval. Remodeling will be deemed to have occurred if the automated dispensing machine or system is changed or replaced, moved to a different room within the approved facility/site or fastened to a new or different permanent structure than initially approved or if the overall physical security of drugs stored in the system is changed as defined in 20 CSR 2220-2.010. Remodeling plans must be provided to the board office thirty (30) days prior to commencing the proposed change along with an affidavit showing any physical changes to the automated dispensing site, structure or location and the projected remodel completion date.

(D) An Out-of-Business Notification form must be filed with the Board within fifteen (15) days of discontinuing service or closing a Class-N system.
(4) Standards of Operation. Class-N automated dispensing systems must be maintained and operated in compliance with applicable state and federal drug laws, including, all controlled substance and patient confidentiality requirements. The system must be maintained in good working order and must properly and accurately function at all times the system is in operation. A pharmacist shall not be required to be physically present on site when the automated dispensing system is in operation if the system is operated in compliance with this rule.

(A) Except as otherwise authorized by law, medication may only be dispensed from a Class-N automated dispensing system pursuant to a patient-specific prescription or a patient-specific medication order.

(B) Prior to initial operation, the system must be tested by a properly qualified pharmacy designee to ensure the system is functioning properly. Additional testing must occur if any modification to the automated dispensing system occurs that changes or alters the dispensing or electronic verification process. Testing dates and results must be documented in the pharmacy’s system.

(C) All transactions regarding the automated dispensing system must be tracked and documented in writing, including, the placement, removal and dispensing of medication into and out of the system.

(D) Medication stocked in an automated dispensing system must be maintained under proper temperature and storage conditions in compliance with Food and Drug Administration (FDA) requirements and manufacturer guidelines. The system must be equipped with an effective temperature measuring device. At a minimum, temperatures must be recorded and documented daily. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that are reviewed daily or if the system provides alerts of improper temperature deviations that are promptly reviewed by a pharmacist. Documentation of the required temperature review or any temperature alerts must be maintained in the pharmacy’s records or otherwise accessible to the pharmacy.

(E) Controlled substances shall be handled and dispensed in compliance with all state and federal controlled substance laws.

(F) Long Term Care. The provisions of 20 CSR 2220-2.140 shall be applicable to a remote dispensing system used in a long-term care facility for emergency dispensing (e.g., an e-kit). All other long-term care dispensing via an automated dispensing system shall comply with the provisions of this rule.

(5) Except as otherwise provided in section (6), a pharmacist shall review and approve all medication dispensed by the automated dispensing system prior to release. A pharmacist may electronically verify medication contents and labels from a remote location if:
1. The entire dispensing process is fully automated from the time the process is initiated until a completed and properly labeled manufacturer unit of use package or medication container is produced that is ready for dispensing;

2. A pharmacist reviews and verifies the prescription or medication order and the patient/medication information used to initiate the dispensing process prior to dispensing;

3. An electronic verification system is used to verify the correct medication and medication strength, dosage form and quantity have been dispensed; and

4. The pharmacist electronically views and verifies the final medication package or container for accuracy prior to dispensing using video or electronic technology. The pharmacist must be able to view and verify the actual package/container, including, the label and medication contents.

(6) Medication may be removed [by a licensed healthcare practitioner] from a Class-N automated dispensing system when a pharmacist is not physically present if:

1. The medication will be used or administered as authorized by section (2) of this rule;

2. The identity of the individual/healthcare practitioner accessing the system is electronically recorded and verified before dispensing using a password or other unique identifier;

3. A pharmacist reviews and approves the initial prescription or medication order. Subsequent refills/doses may be removed from the automated system for the specific patient without additional pharmacist review/approval of the prescription or medication order, however, any change in the prescription or medication order shall require new approval from a pharmacist;

4. The automated dispensing system uses an electronic verification system to verify the correct medication is dispensed;

5. A pharmacist is available to respond to inquiries in the event of an emergency; and

6. A pharmacist operating on behalf of the pharmacy reviews [all] medication dispensed by the system and the applicable prescription/medication order on a [random basis/sample size/weekly/monthly basis] to ensure proper dispensing and compliance with the requirements of the rule. The identity of the reviewing pharmacist, the date of review and the review results must be documented in writing and maintained in the pharmacy’s records for two (2) years.

(C) The final pharmacist prescription/medication order verification requirements of 20 CSR 2220-2.010 shall be deemed satisfied if a pharmacist complies with the requirements of this section.
(7) Labeling. Medication must be labeled in accordance with section 338.059, RSMo, or alternatively labeled with the drug name, strength, expiration date, lot number and, if applicable, beyond-use date. Multi-med paks must comply with 20 CSR 2220-2.145 and must be labeled with the following:

1. The name of the patient;
2. A serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;
3. The name, strength, physical description or identification and total quantity of each drug product contained therein;
4. The directions for use and cautionary statements if any, contained in the prescription order for each drug product therein;
5. Any storage instructions or cautionary statements required by the official compendia;
6. The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date shall be not later than sixty (60) days from the date of preparation); and
7. Any other information, statements, or warnings required for any of the drug products contained therein.

(8) Stocking Medication. Automated dispensing systems may only be stocked by a Missouri licensed pharmacist or by a Missouri licensed intern pharmacist or registered technician. Individuals authorized to stock medication must be trained on system use and operations as appropriate for the tasks performed. A list of individuals authorized to stock the system must be maintained by the pharmacy and available on request of the Board or the Board’s authorized designee.

(A) Medication must be transported to the automated dispensing system in a secure, tamper-evident container. No outdated, expired, misbranded or adulterated medication may be stocked or stored in the system;

(B) The pharmacy must maintain a record of all medication stocked into or removed from the system. At a minimum, the pharmacy’s records must maintain written documentation of the date and time medication is stocked into or removed from the system, the identity of individuals stocking or removing medication and the type of medication stocked/removed.

(C) Automated dispensing systems may be stocked by an intern pharmacist or a pharmacy technician without a pharmacist present if:

1. The system is stocked using manufacturer unit of use packages or prepackaged containers that have been verified by a pharmacist to ensure the container has been properly prepackaged and labeled. The identity of the verifying pharmacist must be documented in the pharmacy’s records; and
2. An electronic verification system or other mechanical system is used to ensure medication and prepackaged containers/cartridges are correctly stocked or loaded into the system.

(D) Medication may be returned and reused as authorized by 20 CSR 2220-3.040 or as authorized by 20 CSR 2220-2.145 governing multi-med dispensing.

(E) Prepackaging must comply with 20 CSR 2220-2.130

(9) Prescription/Medication Order Records. The pharmacy must maintain records of all prescriptions or medication orders dispensed by the automated dispensing system. Prescriptions must be maintained as required by section 338.100, RSMo, and the rules of the Board. For medication orders, the pharmacy’s records must include the dispensing date, patient name, authorized prescriber and the name, strength, dosage form and quantity of medication dispensed. Except as otherwise required by law, prescription and medication order records may be included in a patient medical record maintained by the healthcare facility, provided the records must be retrievable by the pharmacy on request of the Board or the Board’s authorized designee. Prescriptions and medication orders must be assigned a sequential number or other unique identifier that allows individual retrieval of the dispensing record.

(10) Security. Adequate security systems and procedures must be maintained to prevent unauthorized access to or movement of the automated dispensing system and to prevent medication loss, diversion or theft.

(A) Automated dispensing systems must be securely placed inside of a licensed pharmacy or health care facility. The system must be securely fastened to a permanent structure and shall not be located in or near exit doors or accessible to the public.

(B) Automated dispensing systems must be locked by key, combination or other mechanical or electronic means. The system must consist of a substantially constructed container and shall be maintained and operated in a manner that will prevent system theft, tampering or unauthorized use/access. The system must be equipped with an alarm or other monitoring system that notifies or alerts the pharmacy in the event of a security breach or other unauthorized access.

(C) A written list must be maintained of all individuals or entities authorized to access an automated dispensing system. The pharmacist-in-charge must have authority to assign, initiate, modify and deny access to the automated dispensing system as deemed necessary or appropriate. System access must be promptly terminated or revoked if access authorization is revoked or rescinded.
(D) All access to the automated dispensing system must be manually or electronically documented, including, the date and time the system was accessed, the identity of individuals accessing the system and the name, strength, quantity and dosage form of medication placed in or removed from the system.

(E) Any theft or diversion of or from an automated dispensing system must be reported to the Board in writing within fourteen (14) days in a manner designated by the Board. Any suspected or discovered theft or diversion from an automated dispensing system must be promptly investigated and prompt corrective action taken to prevent future theft or losses.

(F) [The pharmacy must reconcile medication inventory for each automated dispensing system every six ??? months.] A perpetual inventory must be maintained for any automated dispensing system that stocks or provides controlled substances. [Controlled substance inventory must be reconciled every ?? months.] The required inventory and reconciliation must be documented in writing and retained for two (2) years. Should all inventory have to be reconciled?

(11) Quality Assurance. An initial and ongoing quality assurance program must be operated and established to objectively and systematically monitor the appropriate use and performance of all automated dispensing systems. The quality assurance program must include policies and procedures for detecting, evaluating and documenting system malfunctions and any breach of security.

(A) Quality assurance testing must be conducted [weekly/monthly/every six (6) months] for each automated dispensing system to measure system accuracy and operations. At a minimum, the required testing must include a physical inspection of drugs in the system and testing of the electronic verification system. Retesting must be performed whenever any upgrade or change is made to the system that may affect, alter or change system security, medication release/dispensing or the electronic verification system.

(B) As part of the quality assurance program, a pharmacist must review and investigate any verified or suspected dispensing or labeling error related to the automated dispensing system. The investigation dates and results must be documented in the pharmacy’s records. If a dispensing error is verified or substantiated, operation of the system must immediately cease until the system has been restored to proper functioning.

(C) Quality assurance documentation shall be maintained for two (2) years, including, documentation of quality assurance testing and testing results.
(12) Policies and procedures. The pharmacy shall establish and follow written policies and procedure to ensure the proper, safe, and secure functioning of all automated dispensing systems. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy’s records for a minimum of two (2) years. The required annual review shall be documented in the pharmacy’s records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for—

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

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

(C) Monitoring and ensuring accurate dispensing;

(D) Reporting, investigating, and addressing known or suspected errors and system malfunctions;

(E) Testing the accuracy of the automated dispensing system and any accompanying electronic verification system;

(F) Training persons with system access on proper equipment use and operations;

(G) Tracking, documenting and investigating medication errors;

(H) Conducting routine and preventive maintenance and, if applicable, calibration;

(I) Removing expired, adulterated, misbranded, or recalled drugs;

(J) Preventing unauthorized access to the system, including, assigning, discontinuing, restricting or changing security access as deemed necessary or appropriate;

(K) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;

(M) Maintaining the quality assurance program required by section (10) of this rule;

(N) Securing and accounting for wasted or discarded medications;

(O) Providing any required notifications to the board or other state or federal agency; and

(P) Emergency procedures in the event of a disaster or power outage that affects system functioning, including, procedures for system recovery.
338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.
2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a supervision agreement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a
board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

12. In addition to other requirements established by the joint promulgation of rules by the board of pharmacy and the state board of registration for the healing arts:

(1) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);

(2) A pharmacist who is administering a vaccine shall request a patient to remain in the pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions. Such pharmacist shall have adopted emergency treatment protocols;

(3) In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon completion, and shall display the certification in his or her pharmacy where vaccines are delivered.

13. A pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient's primary health care provider, if provided by the patient, containing:

(1) The identity of the patient;

(2) The identity of the vaccine or vaccines administered;

(3) The route of administration;
(4) The anatomic site of the administration;

(5) The dose administered; and

(6) The date of administration.


Prior revisions: 1929 § 13140; 1919 § 4712; 1909 § 5764
338.165. 1. As used in this section, the following terms mean:

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

(2) "Hospital", a hospital as defined in section 197.020;

(3) "Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system;

(4) "Medical staff committee", the committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management;

(5) "Medication order", an order for a legend drug or device that is:

    (a) 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

    (b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;

(6) "Patient", an individual receiving medical diagnosis, treatment or care at a hospital or a hospital clinic or facility.

2. The department of health and senior services shall have sole authority and responsibility for the inspection and licensure of hospitals as provided by chapter 197 including, but not limited to all parts, services, functions, support functions and activities which contribute directly or indirectly to patient care of any kind whatsoever. However, the board may inspect a class B pharmacy or any portion thereof that is not under the inspection authority vested in the department of health and senior services by chapter 197 to determine compliance with this chapter or the rules of the board. This section shall not be construed to bar the board from conducting an investigation pursuant to a public or governmental complaint to determine compliance by an
individual licensee or registrant of the board with any applicable provisions of this chapter or the rules of the board.

3. The department of health and senior services shall have authority to promulgate rules in conjunction with the board governing medication distribution and the provision of medication therapy services by a pharmacist at or within a hospital. Rules may include, but are not limited to, medication management, preparation, compounding, administration, storage, distribution, packaging and labeling. Until such rules are jointly promulgated, hospitals shall comply with all applicable state law and department of health and senior services rules governing pharmacy services and medication management in hospitals. The rulemaking authority granted herein to the department of health and senior services shall not include the dispensing of medication by prescription.

4. All pharmacists providing medication therapy services shall obtain a certificate of medication therapeutic plan authority as provided by rule of the board. Medication therapy services may be provided by a pharmacist for patients of a hospital pursuant to a protocol with a physician as required by section 338.010 or pursuant to a protocol approved by the medical staff committee. However, the medical staff protocol shall include a process whereby an exemption to the protocol for a patient may be granted for clinical efficacy should the patient's physician make such request. The medical staff protocol shall also include an appeals process to request a change in a specific protocol based on medical evidence presented by a physician on staff.

5. Medication may be dispensed by a class B hospital pharmacy pursuant to a prescription or a medication order.

6. A drug distributor license shall not be required to transfer medication from a class B hospital pharmacy to a hospital clinic or facility for patient care or treatment.

7. Medication dispensed by a class A pharmacy located in a hospital to a hospital patient for use or administration outside of the hospital under a medical staff-approved protocol for medication therapy shall be dispensed only by a prescription order for medication therapy from an individual physician for a specific patient.

8. Medication dispensed by a hospital to a hospital patient for use or administration outside of the hospital shall be labeled as provided by rules jointly promulgated by the department of health and senior services and the board including medication distributed for administration by or under the supervision of a health care practitioner at a hospital clinic or facility.
9. This section shall not be construed to preempt any law or rule governing controlled substances.

10. Any rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall only become effective if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly under chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2014, shall be invalid and void.

11. The board shall appoint an advisory committee to review and make recommendations to the board on the merit of all rules and regulations to be jointly promulgated by the board and the department of health and senior services pursuant to the joint rulemaking authority granted by this section. The advisory committee shall consist of:

   (1) Two representatives designated by the Missouri Hospital Association, one of whom shall be a pharmacist;

   (2) One pharmacist designated by the Missouri Society of Health System Pharmacists;

   (3) One pharmacist designated by the Missouri Pharmacy Association;

   (4) One pharmacist designated by the department of health and senior services from a hospital with a licensed bed count that does not exceed fifty beds or from a critical access hospital as defined by the department of social services for purposes of MO HealthNet reimbursement;

   (5) One pharmacist designated by the department of health and senior services from a hospital with a licensed bed count that exceeds two hundred beds; and

   (6) One pharmacist designated by the board with experience in the provision of hospital pharmacy services.

12. Nothing in this section shall be construed to limit the authority of a licensed health care provider to prescribe, administer, or dispense medications and treatments within the scope of their professional practice.

(L. 2014 S.B. 754 merged with S.B. 808)
# Rules of Department of Insurance, Financial Institutions and Professional Registration

## Division 2220—State Board of Pharmacy

### Chapter 6—Pharmaceutical Care Standards

<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 CSR 2220-6.030 Provision of Drug and/or Medical Information</td>
<td>3</td>
</tr>
<tr>
<td>20 CSR 2220-6.040 Administration by Medical Prescription Order</td>
<td>3</td>
</tr>
<tr>
<td>20 CSR 2220-6.050 Administration of Vaccines Per Protocol</td>
<td>4</td>
</tr>
<tr>
<td>20 CSR 2220-6.055 Non-Dispensing Activities</td>
<td>5</td>
</tr>
<tr>
<td>20 CSR 2220-6.060 General Provisions</td>
<td>6</td>
</tr>
<tr>
<td>20 CSR 2220-6.070 Certificate of Medication Therapeutic Plan Authority</td>
<td>6</td>
</tr>
<tr>
<td>20 CSR 2220-6.080 Medication Therapy Services By Protocol</td>
<td>7</td>
</tr>
<tr>
<td>20 CSR 2220-6.100 Pharmacy Standards for Dispensing Blood-Clotting Products</td>
<td>9</td>
</tr>
</tbody>
</table>
(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.


20 CSR 2220-6.060 General Provisions

PURPOSE: This rule establishes definitions for 20 CSR 2220-6.060 to 20 CSR 2220-6.080 governing medication therapy services by pharmacists.

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(A) Authorizing physician(s)—The physician identified in the written protocol as authorizing medication therapy services;

(B) Health care entity—For purposes of this rule, a health care entity shall be defined as any entity or organization that is licensed or certified by the state or federal government as a hospital, 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 as defined by Chapter 630, RSMo, and that is required to maintain patient medical records by state or federal law;

(C) Medication therapy protocol—A written agreement between a physician and a pharmacist for the provision of medication therapy services. A medication therapy protocol shall comply with the provisions of 20 CSR 2220-6.080;

(D) Medication therapy services—The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient’s medication therapy or device usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080, modification shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication therapy management that does not include the initiation or implementation of a modification of medication therapy, as provided herein;

(E) Pharmacy resident—A Missouri-licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists;

(F) Prescription order for medication therapeutic plan—A lawful order that is issued by the authorizing physician within the scope of his/her professional practice for the provision of medication therapy services by a pharmacist for a specific patient, including, patients of a health care entity; and

(G) Protocol—A medication therapy protocol, as defined herein.

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


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 postgraduate 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;
6. Evaluating treatment progress;
7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
8. Medication reconciliation;
9. Drug utilization review;
10. Applicable state or federal law;
11. Formulating and documenting personal medication records;
12. Documenting clinical outcomes;
13. Interpreting, monitoring, ordering, and assessing patient test results; and

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

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


20 CSR 2220-6.080 Medication Therapy Services By Protocol

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

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

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

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

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

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

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

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

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

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

(3) Authorizing Physician Requirements.

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

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

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

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

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

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

(4) Protocol Requirements.

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

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

1. The identity and signatures of the authorizing physician and pharmacist;
2. The effective dates of the protocol;
3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug categories included in the written protocol and the type of medication therapy services allowed in each case;

4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting medication therapy services;

5. Procedures for documenting medication therapy decisions made by the pharmacist and a plan for communication, feedback, and reporting to the authorizing physician concerning specific decisions made;

6. A mechanism and procedure that allows the authorizing physician to override, rescind, modify, or otherwise amend the protocol. All modifications or amendments to the protocol shall be documented in writing, signed, and dated by all involved parties prior to the implementation of such modification or amendment. The protocol may be immediately rescinded by the authorizing physician or the pharmacist with or without cause, provided the rescission is documented in writing. If any conflict arises regarding the professional judgment of the pharmacist and physician with regard to the subject of the medication therapy services, the physician has ultimate authority;

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

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

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

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

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

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

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

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

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

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

1. Assessing patient-specific data and issues;

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

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

4. Modifying and monitoring medication regimens;

5. Evaluating treatment progress;

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

7. Medication reconciliation;

8. Drug utilization review;

9. Formulating and documenting personal medication records;

10. Documenting clinical outcomes;

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

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

13. Patient education and counseling.

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) A pharmacist shall be deemed in compliance with the notification requirements of this rule if the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, as defined by this rule, and documentation of the notifications required by this section is recorded in a patient medical...
(D) Notifications required by this section shall be in writing unless otherwise authorized by the authorizing physician.

(6) Modifying Drug Therapy.

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

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

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

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

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

(7) Record Keeping.

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

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

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

3. Any pertinent assessments, observations, or findings;

4. Any diagnostic testing recommended or performed;

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

6. Referrals to the authorizing physician;

7. Referrals for emergency care;

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

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

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

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

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

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

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

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

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

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

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


20 CSR 2220-6.100 Pharmacy Standards for Dispensing Blood-Clotting Products

PURPOSE: This rule implements the provisions of section 338.400, RSMo, and establishes pharmacy standards for dispensing...
# MTS Advanced Pharmacy Practice

**January 3, 2017**  
9am – 1pm  
UMKC Pharmacy – Health Sciences Building Room 5309

<table>
<thead>
<tr>
<th>Topic</th>
<th>Duration</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introductions</td>
<td>10 minutes</td>
<td></td>
</tr>
<tr>
<td>Background</td>
<td>15 minutes</td>
<td>Bert McClary</td>
</tr>
<tr>
<td>MSHP PAI Collaborative Practice Survey</td>
<td>15 minutes</td>
<td>Amanda Hays and Melissa Gabriel</td>
</tr>
<tr>
<td>Discussion</td>
<td>30 minutes</td>
<td>Group</td>
</tr>
<tr>
<td>Break</td>
<td>10 minutes</td>
<td></td>
</tr>
<tr>
<td>Goals</td>
<td>45 minutes</td>
<td>Group</td>
</tr>
<tr>
<td>Challenges/Obstacles</td>
<td>45 minutes</td>
<td>Group</td>
</tr>
<tr>
<td>Break</td>
<td>10 minutes</td>
<td></td>
</tr>
<tr>
<td>Next Steps/Planning</td>
<td>50 minutes</td>
<td>Group</td>
</tr>
<tr>
<td>Wrap up</td>
<td>10 minutes</td>
<td></td>
</tr>
</tbody>
</table>

**Additional Instructions:**  
[Use this section for additional instructions, comments, or directions.]
Medication Compounding Certification Option
The Joint Commission has evaluated sterile and non-sterile medication compounding practices for many years during its accreditation surveys. However, more recently we have received considerable feedback from our accredited customers indicating the need for a more focused and specialized evaluation of the facilities' compounding practices that would also serve to meet the expectations of regulatory oversight bodies. With the needs of our customers in mind, we have decided to develop an optional Medication Compounding Certification Program that will greatly enhance the depth and specificity with which we evaluate compounding practices. The basis for the enhanced standards are the sterile and non-sterile compounding requirements issued by the United States Pharmacopeia (USP) in its chapters <797> and <795>. Compliance with the standards will be assessed by pharmacist surveyors that have undergone specific training in evaluating USP compliance. Facilities performing compounding pharmaceuticals services may elect to pursue this optional certification, which is scheduled to launch in January of 2017.

Facts about the Medication Compounding Certification Program:

Eligibility – Joint Commission’s Medication Compounding Certification (MDC) can be achieved by hospital pharmacies or home care pharmacies that provide sterile and non-sterile compounding services.
Note: This certification option is available to non-accredited organizations.

Award Length – Two years

Certification Standards – MDC standards are based on the sterile and non-sterile compounding requirements issued by the United States Pharmacopeia (USP) in its chapters <797> and <795>. When chapter <800> is published later in 2017, those requirements will be added to the MDC program.

Review Process - Compliance with the standards will be assessed during an on-site review conducted by pharmacist reviewers that have undergone specific training in evaluating USP compliance.

Review length - 1-2 days for most pharmacies depending upon the number of locations in your organization conducting sterile compounding services

Pricing - The total estimated certification fees are projected to be $10,000, which include 2 annual fees ($3600 each) and one on-site review fee ($2,000 for the first day, $800 each additional day that may be needed).

Pricing is projected based on assumptions about the Certification review length. Actual review days/length may vary, based on the number of locations where compounding pharmacy services are provided. Actual fees may vary based on the review duration.

Consideration for State Hospital Associations
This past summer the Michigan Hospital Association reached out to the Joint Commission as their state had passed a Compounding Pharmacy Law that included a provision requiring
pharmacies that perform sterile compounding services to obtain accreditation from one of two other national accrediting bodies. The law required the pharmacies to have an application submitted prior to October 1, 2016. The Michigan Hospital Association’s members had expressed a desire to have the Joint Commission be their accreditor of choice for Compounding pharmacy services, however given that we did not yet have a program, the Joint Commission was not named as one of the approved accrediting bodies. At that time the Joint Commission was in the process of developing a certification program for Medication Compounding, but it was not anticipated to launch until January 2017. With assistance from the Michigan Hospital Association the Joint Commission was able to present the details of our anticipated program to the Michigan Board of Pharmacy for their consideration and the Board did approve the Joint Commission’s Medication Compounding certification program as a viable option for pharmacies in meeting the accreditation requirement of the law. We implemented a fast track process for Michigan pharmacies to allow them to apply prior to the deadline, and will conduct over 80 Medication Compounding reviews in the first half of 2017 allowing Michigan hospital pharmacies the ability to meet the June 31, 2017 accreditation deadline put forth by the Board of Pharmacy.

Like Michigan, many state legislatures and Boards of Pharmacy are moving forward with requirements for pharmacies that perform sterile compounding services to be compliant with USP <797>. Some state Boards are conducting their own inspection for USP compliance, and others are looking to national accrediting bodies to conduct the onsite reviews. If your state begins to look at mandating compliance with USP for your hospital’s pharmacies, please, feel free to reach out to Jennifer Hoppe (630-792-5261) or Mark Crafton (630-792-5260) on how we might collaborate with your association to ensure that your members have the option of using the Joint Commission’s Medication Compounding certification to satisfy an accreditation/certification mandate, or in lieu of the state inspection for compliance with USP.

**SAFER Matrix**
Survey Analysis for Evaluating Risk (SAFER) Matrix goes in effect January 1, 2017 for all programs. The SAFER matrix is a new scoring model that recognizes that the potential for an Element of Performance (EP) to be related to a risk/safety issue depends on the context of the situation during a given survey/review and not pre-determined based on the EP itself. The SAFER matrix uses two components of risk (likelihood to harm and scope) to identify the potential level of risk associated with a given survey finding, resulting in one, comprehensive visual representation of all survey findings. As the SAFER Matrix rolls out to all programs next month, the primary changes affecting your members include:

- The SAFER matrix will be generated and embedded within the survey process and the final report
  - Surveyors will use operational definitions to help guide placement in the matrix (see January 2017 perspectives for definitions)
- All Requirements for Improvement (RFIs) due in a 60 day Evidence of Standards Compliance (ESC)
  - Elimination of Direct and Indirect EP designations
  - 45 day ESC no longer applicable (one exception, Preliminary Denial of Accreditation (PDA) decisions will still require 45 Day ESC)
- All findings will now require the submission of an ESC
  - Opportunities for Improvement (OFI) section of the report no longer applicable
  - Elimination of A and C EP categories
  - Elimination of requirement to complete a Measures of Success (MOS)
Findings of higher risk will require two additional performance improvement components to be submitted with the 60 day ESC

- Leadership Involvement
- Preventative Analysis

Changes to the Clarification Process

After a survey event, organizations have the opportunity to submit clarifying evidence if they believe that their organization was in compliance with a particular standard at the time of survey. A review of data from the past 18 months identified that 50% of hospitals request clarifications after survey. To better understand the drivers behind the high volume of requests, we conducted a deeper dive into the issues. Three root causes emerged in the analysis:

1. Lack of Documentation
2. Interpretation Issues
3. Survey Process Issues

Given the high volume of clarification requests, this process can be time and resource intensive, and at times can represent a misdirection of resources. In addition, the current process can also undermine the survey process and surveyors. Therefore, one of the Project REFRESH initiatives focused on improving the clarification process with these factors in mind. The Joint Commission will implement three changes to the clarification process effective January 1, 2017 (see December 2016 Perspectives for full article):

1. **Clerical Errors.** Findings with clerical errors will no longer be removed from the report. If a clerical error is noted in a survey finding post survey, the organization can submit a Clarification Request for clerical error to be corrected, however the corrected Requirement for Improvement (RFI) will remain in the report and be an action item for the ESC process.

2. **Audit Option.** With the elimination of the Category C EPs the audit option will no longer be part of the clarification process

3. **Lack of Documentation.** RFIs due to lack of required documentation at the time of survey will no longer be eligible for the clarification process. If the required documentation is not available at the time of survey, the organization will be cited accordingly and will need to submit an ESC for the RFI. We will no longer accept proof of documentation post-survey to have the RFI removed from the report.

We understand that these modifications represent a significant change in the post survey process, however we also believe that implementing these changes will allow organizations the ability to focus their resources on true performance improvement activities following the survey. To help organizations prepare for the documentation requirements of survey we have developed an optional survey checklist of the documents that are required to be current and available during survey. This optional tool is posted on the organization’s extranet site.

The other contributing factors identified by the analysis of the clarification request data will be addressed through other initiatives under Project REFRESH. Initiatives include:

  - When there is debate regarding whether or not a given practice at a facility is compliant with the standards, bringing SIG staff together with the organization and the surveyors at the time of survey to resolve. Idea is to have consensus
between all 3 parties prior to survey exit, removing the need for a clarification altogether.

- Clear hand-off and communication of RFIs (ongoing).
  - How survey findings are communicated can impact the organizations understanding and acceptance of an RFI.

- Pre-survey document review (tentatively scheduled for the end of 2017)
  - Allow customers’ ability to upload key documents prior to survey for Joint Commission review. The current process of onsite review cuts into valuable survey time that would be better spent doing tracers, environmental tours, etc.

Please contact me if you have any questions or comments regarding the information provided in this update. Have a wonderful Holiday season! Looking forward to further collaboration with all of you in 2017.

Jennifer Hoppe
Senior Associate Director, State Relations
jhoppe@jointcommission.org
630-792-5261