OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

June 3, 2016

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

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

Committee Members Absent
Kevin Kinkade, R.Ph.,

Staff Present
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector

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

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

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

James Gray – yes
Greg Teale – yes
Colby Grove- yes
Daniel Good – yes
Neil Schmidt- yes
Kevin Kinkade - absent
A motion was made by Neil Schmidt, seconded by Daniel Good, to approve the May 6, 2016, minutes as presented. The motion passed 5:0:0:1 with roll call vote as follows:
James Gray – yes     Colby Grove – yes     Neil Schmidt - yes
Greg Teale – yes     Daniel Good – yes     Kevin Kinkade - absent

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

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

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

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

Ms. Willson also reported MHA felt it could not adopt/endorse all of the Facility Guideline Institute's (FGI) hospital design and construction standards at this time. MHA will work with DHSS and the Missouri Society for Healthcare Engineering to review FGI
standards and find a solution. Julie Creach indicated DHSS previously intended on adopting the FGI standards but will now need to draft a rule that may incorporate all or portions of the FGI standards. Sarah Willson commented that nothing prevents an entity from voluntarily following the FGI guidelines or a more current standard which is what many entities have done. However, Ms. Willson spoke favorably of DHSS being able to enforce and survey to newest standards.

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

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

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

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

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

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

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

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

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

- In further discussion, Kimberly Grinston noted the current draft administration rule focuses on who the practitioner is operating on behalf of. Tom Glenski suggested limiting section (10) of the draft to individuals operating on behalf of a health care entity. James Gray alternatively suggested including persons operating on behalf of a health care entity "or as determined by the Board" to give the Board discretion. Bert McClary asked if the rule should include the definition of hospital and hospital clinic or facility from SB 808 enacted in 2014.
Consensus to add the definitions of hospital and hospital clinic and facility from SB 808 and to add "other facilities recognized by the Board."

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

**Agenda Item #9:** Kimberly Grinston reported the office is working on a draft guidance to address many of the jurisdictional and practice concerns the Committee previously discussed. Ms. Grinston indicated the draft guidance would be returned to the Committee for additional review/comment at a future meeting. Greg Teale indicated he surveyed his peers and asked them to rate their pharmacy related concerns by priority/level of importance. Mr. Teale indicated the following concerns were submitted:

1. Labeling: Concerns were raised that the Class-A labeling requirements were inappropriate for hospital facilities—many of whom are dispensing for immediate use. It was reported that entities such as infusion clinics may be using the hospital's labeling system and wouldn't have information like the pharmacy's address or phone number on the label.

2. Filing Orders: Concerns were raised that medication orders are not kept in a regular prescription file as required for retail pharmacies.

3. Medication Therapy Services/Collaborative Drug Therapy Agreements: Concerns were raised that the MTS rules require an agreement between the pharmacist and physician although some Class-B pharmacies may be using a P&T protocol. Concerns were also expressed about the inconsistent standards for pharmacists who may be fluctuating between DHSS regulated settings and Board regulated settings. Greg Teale commented the current requirements are both burdensome and confusing when providing patient care.

4. Automated Cabinets: Concerns were raised that pharmacy controlled automated cabinets may be the primary means of distribution for some Class-B pharmacies in lieu of transferring stock to a cabinet for physician dispensing. James Gray noted these medications stay under the control of the pharmacy. Greg Teale indicated the automated cabinets use technology to enhance accuracy and prevent diversion and that cabinet activity is verified by a pharmacist. Mr. Teale asked the Board to consider how these cabinets may be operated lawfully and still stay under pharmacy control.

Additional discussion was held regarding remote/video monitoring of technician activities. Tom Glenski reported the Board has previously indicated that remote final product verification is not allowed. James Gray suggested that the Board reconsider this issue and asked what the Board's concerns would be if the data shows a higher degree of accuracy with remote/electronic verification. Tom Glenski added the Board has been reluctant to address expanded duties for technicians until technician education or training requirements are in place.
5. Pharmacy Access: Concerns were raised regarding access to the pharmacy by other healthcare practitioners. Greg Teale indicated there may be a need for nurses to access the pharmacy to draw doses or access medication when the pharmacy is closed. Tom Glenski indicated Missouri law says these nurses may need to be a technician but noted the Board has never officially addressed this topic for nurses entering Class-B pharmacies. Bert McClary suggested there would be value in allowing access for nursing staff and other healthcare practitioners in lieu of stocking medication outside of the pharmacy.

6. Concerns were raised regarding USP chapters 797 and 800. However, Greg Teale indicated this may not need priority consideration at this time. Tom Glenski noted the Board’s requirements are generally stricter than DHSS’ requirements. Mr. Glenski mentioned the previously discussed white-bagging issue and indicated the Board wrote a rule that may address this. James Gray commented there is general confusion about what is allowed under a Class-J arrangement.

7. Mr. Teale noted he will discuss the proposed webinar questions with his contact group and will try to have feedback before June 20th.

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

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

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

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

**Agenda Item #12:** Kimberly Grinston reported on pending legislation listed in the agenda and noted there have been extensive discussions regarding the value of a PDMP. Neil Schmidt inquired about proposed legislation that would allow pharmacists
to dispense contraceptives; Kimberly Grinston reported she does not believe the legislation passed but will update the Committee if different.

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

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

Date Approved: 9/28/2016
20 CSR 2220-6.040 Administration by Medical Prescription Order

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

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

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

(A) “Health Care Entity”- A health care entity shall include any entity or organization, other than a pharmacy licensed under Chapter 338, RSMo, that is licensed or certified by the state or federal government to provide health care services and that is required to maintain patient medical records by state or federal law.

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

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

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

(A) Hold a current, unrestricted license to practice pharmacy in this state;
(B) Hold a current provider level cardiopulmonary resuscitation (CPR) Basic Life Support certification (BLS) issued by the American Heart Association or the American Red Cross or an equivalent organization. The certificate program must include a live training component;

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

1. Physiology and techniques for routes of administration which must include hands-on training in all routes of administration the pharmacist utilizes;

2. Drug storage and handling;

3. Informed consent requirements, if applicable;

4. Pre- and post-administration assessment and counseling;

5. Biohazard waste disposal; and

6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks; and

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

(E) Maintain documentation of the above requirements; and

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

(4) General Requirements.

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

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

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

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

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

(E) Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.
(F) For pharmacists administering drugs in a health care entity, the policy and procedure review required by this subsection may be performed by the pharmacist-in-charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the health care entity responsible for reviewing clinical practices.

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

(A) The name of the licensed prescriber authorized practitioner issuing the order;

(B) The name of the patient to receive the drug;

(C) The name of the drug and dose to be administered;

(D) The route of administration;

(E) The date of the original order; and

(F) The date or schedule, if any, of each subsequent administration; and

(G) A statement that the drug is to be administered by a pharmacist.

(6) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy. For drugs administered by a pharmacist for or on behalf of a health care entity, the information required herein may be recorded in a patient medical record that the health care entity is required to maintain under state or federal law.

1. The name, address, and date of birth of the patient;

2. The date, route, and anatomic site of the administration;

3. The name, dose, manufacturer, lot number, and expiration date of the drug. The lot number shall be documented and recorded for vaccines and biologics;

4. For vaccines, the name and address of the patient’s primary health care provider, as identified by the patient. The pharmacist shall document in the patient’s immunization record if a patient’s primary health care provider is unknown or not designated by the patient;

5. The name or identifiable initials identity of the administering pharmacist. If administered by an intern pharmacist, the identity of the intern and the supervising pharmacist; and

6. The nature of an adverse reaction and who was notified, if applicable.
7. A patient’s refusal or failure to remain in or return to the pharmacy as requested after vaccine administration to observe any adverse reactions; and
8. Written or electronic documentation that required notifications have been sent.

(B) All records required by this regulation rule shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. Records may be securely stored offsite at a location designated by the pharmacy, provided records must be produced as provided in section (11) of this rule.

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

(7) (8) Notification Requirements.

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

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

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

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.
(D) Documentation that the required notifications have been sent must be kept at the pharmacy or other authorized location where the prescription order is maintained.

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

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

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

(10) Administration in a Health Care Entity- Pharmacists administering drugs in a health care entity shall comply with the requirements of this rule with the following exceptions:

(A) A pharmacist shall be deemed in compliance with the requirements of sections (5), (6), (7) and (8) of this rule if the pharmacist administers drugs for or on behalf of a health care entity in compliance with this section and the administration is lawfully recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law.

(B) In lieu of completing a certificate program in the administration of drugs as required by section (4) of this rule, pharmacists administering in a health care entity shall be trained in administration and meet all competency, training and evaluation requirements required by the health care entity and the Missouri Department of Health and Senior Services (DHSS). At a minimum, pharmacist administration training must be similar to or include the training components identified in section (5)(C).
(C) If a pharmacist wishes to administer drugs by a route of administration not included in the original training program, the pharmacist shall first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of the required training shall be maintained at the pharmacy and available to the Board upon request.

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

(E) The policy and procedure review required by section (5) may be performed by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the health care entity responsible for reviewing clinical practices.
