OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting Conference Call

November 18, 2016

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., Member

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: