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 *(via telephone)*
- Colby Grove, R.Ph., Member *(via telephone)*
- Neil Schmidt, R.Ph., Member
- Greg Teale, R.Ph., Member

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

**Others Present**
- William Koebel, Missouri Department of Health and Senior Services
- Sarah Willson, Missouri Hospital Association
- David Wolfrath, MSHP

Chairman McClary opened the meeting at approximately 10:02 a.m. and roll-call was taken.

**Agenda Item # 2 (Board Updates):** Kimberly Grinston reported the Board is in the process of reviewing multiple rules that may be of interest to the Committee, including, the automated dispensing rule, the Class-N: Automated Dispensing System (Health Care Facility) rule and the Class-O: Automated Dispensing System (Ambulatory Care) rule. Committee feedback has been requested.

Neil Schmidt asked about the status of the PDMP legislation. Ms. Grinston indicated the current proposals have language that may be problematic for implementation, however, the local jurisdictions are moving forward with a municipal.

**Agenda Item # 3 (DHSS Updates):** William Koebel reported the moratorium on DHSS rules has ended; the proposed hospital rules will be resubmitted for approval under the
new criteria announced by the Governor’s office. Sarah Willson asked how the rule process has changed. Mr. Koebel indicated there is now an extended questionnaire that must be completed. Committee discussion held; the Committee expressed strong support for filing the revised hospital rules as soon as possible.

**Agenda Item # 4 (Approval of Minutes):** The January 13, 2017, minutes included in the agenda were presented for approval. A motion was made by Greg Teale, seconded by Neil Schmidt, to approve the January 13, 2017, minutes. The motion passed 3:0:0:3 with roll call vote as follows:

- James Gray – absent
- Colby Grove - yes
- Neil Schmidt - yes
- Greg Teale – yes
- Daniel Good – absent
- Kevin Kinkade - absent

**Agenda Item # 5 (Class-B Concept Draft):** Ms. Grinston asked for comments on the Class-B rule concept draft. Mrs. Grinston advised the language is not an official staff or Board recommendation but was intended to guide the Board in drafting future rule requirements. The following Committee discussion was held:

- Ms. Grinston indicated the definition of a dually operated pharmacy was mistakenly removed and would be added in.
- Mr. McClary suggested referencing licensed health care “practitioners” instead of “professionals.” Sarah Willson noted the current trend is to not use the word “provider” while Neil Schmidt noted the Joint Commission uses the term “licensed independent professional.” Committee members suggested specifically referencing advanced practice registered nurses and/or “individuals authorized to prescribe or administer medication.” Discussion held; Committee consensus to reference “licensed healthcare professional.”
- Discussion was held on section (2)’s definition of the pharmacy permit area. Neil Schmidt and Bert McClary asked if the language would allow licensure of a satellite pharmacy under a single permit. Bert McClary noted hospitals may not be aware of the notification requirement for pharmacy remodeling. The Committee questioned the draft language for Class-B pharmacies sharing space with a DHSS hospital pharmacy and asked if there was a difference between “commingled” and “shared inventory.” In lieu of referencing commingled/shared inventories, Sarah Willson suggested amending the language to provide that entities choosing to share inventories must maintain records of all medication transactions. Committee consensus to tentatively revise the language as suggested and review at a future meeting. Bert McClary noted there is difference between a shared site and shared inventory and suggested the Committee use caution when referencing these concepts.
- Kimberly Grinston noted the Board’s medication therapy services (MTS) rule will be revised separately and advised against including MTS changes in the Class-B rule for consistency purposes.

COMMITTEE MEMBER JAMES GRAY JOINED THE MEETING VIA CONFERENCE CALL AT 10:51 A.M.
(Class-B Discussion Continued):  Section (3)(A)- Ms. Grinston asked if a sink or water supply should be required. James Gray noted there may be instances where the sink or water may be directly across the hall and not in the actual patient care area for logistical or sanitation purposes. Mr. Gray noted some Class-B pharmacies may only be dispensing prepackaged medication that is already labeled. David Wolfrath noted some compounding areas may not have hot and cold water in the actual room. Committee consensus to revise the language to accommodate Class-B pharmacies that do not have an in-room sink but have a water supply available. William Koebel also suggested removing the word “appropriate” because it is ambiguous and may present legal concerns.

Section (3)(B): Greg Teale asked how “open to the public” is defined; Mr. McClary asked if the term would include employee prescriptions. Committee discussion held; Consensus to remove “open to the public.” Kimberly Grinston discussed possibly addressing this issue in the general pharmacy standards rule, 20 CSR 2220-2.100.

Section (4)(A)- Committee discussion held; Consensus to amend l. 62 to provide “Medication given to a Missouri licensed healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy....”

Section (4)(B)- Committee discussion held; Committee consensus to include the following labeling language: “Medication will not be considered to have been dispensed for offsite use/administration if administration is initiated onsite but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.”

Section (5): Tom Glenski noted the language conflicts with DHSS’ current rule/interpretation which allows nurses to access a pharmacy to prepare medication for take-home use when pharmacy services are not available. Mr. Glenski noted section (5) would prohibit the medication from being sent home. Committee discussion held; Sarah Willson suggested amending the opening paragraph of section (5) to provide “Except as otherwise authorized by DHSS....”

Section (5)(C): Kimberly Grinston asked if the dually operated pharmacy language should be removed. Discussion held; Committee consensus to make the section applicable to all Class-B pharmacies. Greg Teale suggested the rule clearly state that the pharmacist-in-charge has authority to allow or restrict access; Sarah Willson questioned if pharmacy access needed to be separately identified in the rule. Tom Glenski noted the Board’s pharmacist-in-charge rule already provides the PIC is responsible for determining pharmacy access.

Section (5)(A)(3): Tom Glenski noted the verification and labeling requirements would apply to any filled prescription, including, prescriptions filled for patient use. Mr. Glenski noted this would be an expansion of current Board policy.
James Gray suggested amending the section to address medication for onsite administration.

Committee consensus to revise as suggested and review changes at future meeting.

**Agenda Item # 5 (Review of Class-B Guidance Document):** The following discussion was held:

1. Chairman McClary asked if the proposed language would allow a pharmacist to initiate medication therapy services (MTS) based on a protocol approved by the clinical care committee without an individual prescription order. Committee discussion held. Tom Glenski indicated the Board has informally suggested a separate prescription may not be required. Kimberly Grinston noted this is an open legal question that would need to be officially addressed by the Board.

2. Neil Schmidt suggested the language clearly indicate the guidance is only applicable to pharmacy/medication therapy services under the Board’s jurisdiction. James Gray agreed, however, Mr. McClary noted legal questions still exist on the scope/applicability of the Board’s MTS rules. Ms. Grinston reported the Board’s general counsel indicated it may be inappropriate for him to advise the Committee because of a possible conflict of interest. Ms. Grinston will talk with the Division’s legal counsel for further legal guidance. Committee consensus to seek legal clarification and clarify the guidance document as appropriate.

3. Chairman McClary asked for legal clarification on whether a MTS protocol can be initiated by a nurse. Mr. McClary also asked for legal guidance on whether the Board’s MTS rules would apply if a pharmacist operating under DHSS’ jurisdiction modifies medication that will be eventually dispensed as a prescription. Ms. Grinston asked if the question is under DHSS’ jurisdiction. Mr. Teale indicated clarification is important for hospitals like his that are primarily operating under DHSS’ jurisdiction but also providing pharmacy services under the Board’s jurisdiction (e.g., infusion centers).

4. Mr. Teale suggested the guidance document emphasize that a Class-B pharmacy permit is required if technicians will be used to assist in non-dispensing functions. Mr. Teale further asked if the distribution chart would be included in the final document; Kimberly Grinston indicated the chart became too difficult to follow after the additions added at the last Committee meeting and would be removed.

5. Kimberly Grinston noted Board member Barbara Bilek suggested alternative language for addressing medication that will be initially administered onsite but continued offsite via a pump or other implantable device. Greg Teale commented that not all administration devices are “locked”. Neil Schmidt asked how the language would apply to an insulin pump. Committee discussion held; Consensus to revise the proposed language to provide: “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 programmed external or implanted medical delivery device.” Bert
McClary advised this language should be consistent throughout the guidance document.

COLBY GROVE LEFT THE CONFERENCE CALL AT 11:45 A.M.

Agenda Item # 6 (Missouri MTS Rule): The following Committee discussion was held:

- Bert McClary reported an informal group recently met to discuss the expansion of pharmacy practice, including, pharmacist MTS activities. The initial meeting representatives from MSHP and MPA; Tom Glenski and Christian Tadrus also attended on behalf of the Board for informational purposes. Mr. McClary reported the group discussed legislative options that included: (1) removing the individual patient prescription requirement for MTS services and (2) allowing modification of controlled substances. Mr. McClary reported draft language has been circulated; MPA offered to assist with the legislative process and will be discussing the proposal at their upcoming meeting. Mr. McClary noted the draft language might be added to an existing bill or filed as an independent bill during the current session.

- 20 CSR 2220-6.060: Bert McClary suggested defining a “health care entity” as a hospital clinic or facility as defined by 338.165, RSMo. Mr. McClary also suggested clarifying what it means to create a prescription. Specifically, Mr. McClary suggested amending the rule to clearly provide that a pharmacist can phone-in or send an electronic prescription but cannot create a prescription in their own name.

- 20 CSR 2220-6.080: The following Committee discussion was held:
  a. Section (1)(B): Bert McClary suggested revising this section to provide the protocol must be with an “authorized” physician to clarify that the physician must still meet minimum criteria.
  b. Section (2)(A): Bert McClary suggested simplifying the language and removing redundant references. Mr. McClary also suggested using “medication therapy services” in lieu of a medication therapy plan unless required by statute.
  c. Greg Teale questioned the requirement for a physician order and commented a separate physician order is not always issued in hospitals. Committee discussion held; Consensus to recommend modifying the statute to accommodate actual practice and allow seamless patient care.
  d. Section (3)(A): Bert McClary asked if “current and unrestricted” is necessary and noted some license restrictions may not relate to MTS. Consensus to modify or clarify as suggested.
  e. Section (3)(D): Bert McClary suggested allowing the review of pharmacist MTS activities by the “medical staff committee” as referenced in 338.165, RSMo. Committee discussion held. Greg Teale asked how the 50-mile rule is enforced/interpreted and questioned if the rule accommodates newer telepharmacy/telemedicine practices. Kimberly Grinston noted the 50-mile rule was requested by the Board of Healing Arts. Discussion held;
Consensus to clarify the 50-mile requirement in a Board guidance document.

f. Section (4)(C): Bert McClary asked if the list of MT services should include all of the items currently included in the rule; Mr. McClary noted many of the items listed in this section may be performed without an MTS certificate with the exception of initiating or modifying drug therapy. Mr. McClary further suggested amending the rule to provide the protocol “shall” include initiating or modifying drug therapy. Mr. Glenski noted not all pharmacists may be authorized to initiate therapy. Greg Teale commented section (4) may be confusing for pharmacists practicing across state lines. Committee consensus to remove redundant references and return for future Board review.

g. Section (5)(C): Greg Teale noted this section is imperative for hospitals.

h. Section (6): Bert McClary suggested defining what it means to “create” a prescription in this section. Greg Teale indicated the individual prescription requirement is burdensome for care centers such as infusion clinics.

i. Section (7): Bert McClary suggested clarifying that the pharmacist is responsible for records but the records do not have to be kept in the pharmacy. Greg Teale asked where records would be stored if the pharmacist leaves employment; Tom Glenski indicated the Board would first ask the pharmacist but would still be able to access records held at the pharmacy.

j. Section (11): Bert McClary suggested correcting the rule to reference the administration of medication “by prescription order” and not “by protocol.”

Committee Consensus to revise as suggested and review changes at future meeting.

**Agenda Item # 7 (Automated Distribution Cabinet):** The following Committee discussion was held:

- Committee discussion was held on how the language would affect or coincide with DEA and BNDD requirements for controlled substances. Bert McClary noted DEA originally did not have a rule governing transfers of controlled substances to an automated distribution machine and instead left the issue to the states. Approximately 10 years later, questions were raised regarding transferring controlled substances to another registration. Mr. McClary noted DEA still considers these medications as the pharmacy’s stock but allowed states to set requirements. However, DEA only allowed the practice for long-term care emergency kits. Discussion held; Committee consensus the rule would still be beneficial even if limited to non- controlleds.
- Tom Glenski asked how the rule would affect places that may use a secure bag to dispense medication instead of an actual “automated cabinet.” Bert McClary commented the automated cabinet language might be limiting and noted facilities may not purchase a machine for a small number of drugs. Greg Teale commented facilities may not be able to justify an expensive automated cabinet
in areas like a gastrointestinal lab and may instead use a locked cabinet with some type of signature log. Discussion held. Bert McClary suggested referencing a substantially constructed container similar to DEA. Committee consensus to expand the language to include other non-automated secure cabinets/devices.

- Greg Teale questioned how the Board would define an area “not accessible to the public” and asked if hospitals would comply with the rule if the automated cabinet is in an area that patients may pass or walk through. Neil Schmidt asked if an InstaMed machine in an emergency department would be non-compliant. Tom Glenski noted the goal was to address security issues and to prohibit blatant practices like putting a tackle box on the counter.

Committee consensus to review recommended changes at a future meeting.

**Agenda Item # 9 (Remote Supervision of Pharmacy Technicians):** Kimberly Grinston and Bert McClary noted this issue is still under discussion by the Board and will be discussed at the upcoming April meeting. Greg Teale commented electronic supervision/verification has become more prevalent in hospitals especially in light of new USP Chapter 800 standards. Committee discussion held; Consensus to reconsider after the Board’s April meeting.

**Agenda Item # 10 (Future Agenda Items and Topics):** Discussion held; Consensus to review the Class-B, Class-N, Class-O and MTS revisions at a future meeting along with any updates from the Pharmacy Technician Working Group’s proposal. Sarah Willson asked if the Board needed additional information on automated systems commonly used in hospitals; Committee consensus to provide suggested vendors to the Board office before the April meeting. Further consensus to poll members to determine availability for an April or May meeting.

THE HOSPITAL ADVISORY COMMITTEE ADJOURNED BY CONSENSUS AT 2:35 P.M.

*Kimberly A. Grinston*

________________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved: August 7, 2017