

**OPEN MINUTES**  
**Missouri Board of Pharmacy**  
**Hospital Advisory Committee Meeting**

**Missouri Hospital Association**  
**4712 Country Club Drive**  
**Jefferson City, MO 65102**  
**November 6, 2015**

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 at the meeting. The meeting was called to order by Chairman Bert McClary at 9:04 a.m. on November 6, 2015.

**Committee Members Present**

Bert McClary, R.Ph., Chairman  
Daniel Good, R.Ph., Member  
James Gray, R.Ph., Member  
Neil Schmidt, R.Ph., Member  
Greg Teale, R.Ph., Member

**Committee Members Absent**

Kevin Kinkade, R.Ph., Member

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector

**Others Present**

Christian Tadrus, R.Ph., Board Member  
Sharon Burnett, Missouri Hospital Association  
Julie Creach, Missouri DHSS  
William Koebel, Missouri DHSS  
Dean Linneman, Missouri DHSS  
David Wolfrath, Public Attendee

**Agenda Item # 1:** Chairman McClary welcomed everyone to the meeting and thanked Sharon Burnett for hosting the Advisory Committee at the Missouri Hospital Association's offices.

**Agenda Item # 2:** Kimberly Grinston provided updates on the Board of Pharmacy's revisions to the sterile compounding rule. Ms. Grinston reported the Board voted to review the draft rule language once again in light of the recently released proposed changes to USP 797. A Board subcommittee will likely meet to conduct the review prior to the January meeting.

**Agenda Item # 3:** Dean Linneman reported the Missouri Department of Health and Senior Services (DHSS) did not have any new information/updates for the Advisory Committee.

**Agenda Item # 4:** Sharon Burnett reported the Missouri Hospital Association did not have any new information/updates for the Advisory Committee but indicated Daniel Landon would be introduced later in the meeting.

**Agenda Item # 5:** Daniel Good reported he was present for the 9/25/2015 meeting and requested that the minutes be revised to reflect his attendance and affirmative votes. **A motion was made by Daniel Good, seconded by Neil Schmidt, to approve the minutes with the revisions suggested by Daniel Good. The motion passed 4:0:0:1 with roll call vote as follows:**

James Gray – yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Kevin Kinkade - absent

**Agenda Item # 6:** Bert McClary provided a historical overview of the original DHSS hospital pharmacy rule which was initially promulgated in the 1980s. Bert McClary indicated the current rule draft was completed in 2012 and recommended that the Advisory Committee avoid making unnecessary substantive changes to the rule that might slow down the promulgation process. Mr. McClary indicated the current draft of 19 CSR 30-20.100 was thoroughly vetted in the DHSS' previous rule review meetings that included hospital pharmacists from across the state and state regulators. Dean Linneman indicated the rule is still under legal review and recommended that the Advisory Committee raise any additional concerns prior to the rule being officially filed or forwarded to the Governor's office for approval.

A handout was provided to the Advisory Committee from the Center for Medicare and Medicaid Services (CMS) dated October 30, 2015, relating to "Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications." The following discussion was held:

- Dean Linneman reported the following: DHSS has preliminary reviewed CMS' Guidance which he indicated is not currently effective. The Guidance was not publicly circulated for comment prior to being issued like other CMS documents. Staff will not immediately enforce the Guidance as DHSS does not survey to non-binding interpretive guidelines.
- Bert McClary indicated CMS recently issued similar Guidance documents for critical access hospitals and remarked that the Guidance did not appear to contain anything that would change DHSS' rules. Mr. McClary suggested that the Advisory Committee review the entire CMS hospital services document at a later date to ensure consistency.
- Sharon Burnett remarked the Advisory Committee should pay attention to the information contained in the blue shaded boxes within the Guidance document

because similar information has previously been incorporated into new Conditions of Participation (COPs).

The Working Group proceeded to review DHSS' proposed draft hospital pharmacy rule, 19 CSR 30-20.100. The rule changes recommended by the Advisory Committee have been incorporated into the document attached hereto. In addition to the changes noted therein, the following discussion was also held:

- Section (1): Bert McClary indicated the policy and procedure requirements in the current rule were conglomerated into one section for clarity and also indicated the goal was to use consistent language throughout the professional licensing sections. Neil Schmidt asked if the "qualified" pharmacist requirement was consistent with CMS language and suggested adding a "legally competent" pharmacist which may be referenced in CMS rules. Sharon Burnett recommended that the rule avoid subjective qualifications. Dean Linneman indicated a "qualified" pharmacist would be defined in a separate definitions rule that would be applicable to all DHSS hospital rules.

Sharon Burnett indicated CMS language clarifies that the pharmacist does not have to be on staff full time and suggested that Missouri's rule also clarify that a full-time pharmacist is not required. Bert McClary commented DHSS has never required a full-time pharmacist but noted that "qualified" does not mean the pharmacist-in-charge.

Daniel Good asked if the policy and procedure requirements are consistent with the Board of Pharmacy's rules. Bert McClary commented the applicability of the Board of Pharmacy's rules to hospital pharmacy will have to be clearly addressed at some point. Daniel Good suggested promulgating a comprehensive rule that includes the Board of Pharmacy requirements for entities/pharmacies that are jointly licensed by DHSS and the Board.

- Section (2): James Gray commented the rule should clarify that pharmacy technicians must be licensed in Missouri. Sharon Burnett suggested adding a definition of an intern pharmacist. Discussion was held and changes were made as reflected in the attached document.

- Section (3): Bert McClary opposed including specific pharmacy technician education and training standards in the rule since similar language is not included for other supportive personnel and given the Board of Pharmacy has authority to define technician qualifications. Dean Linneman commented hospitals should show that technicians have been trained in the activities they are actually performing.

- Section (6) & (7): Greg Teale asked about the applicability of these sections to crash carts and if crash carts have to be locked. Bert McClary indicated crash carts must be in an area that is directly supervised and noted it is unclear if that means within sight. Mr. McClary also indicated CMS language provides crash carts must be under "direct supervision" or in a locked area. Sharon Burnett commented CMS' language requires a locked area "when appropriate." Neil Schmidt remarked that requiring crash carts to be in a locked area/room may defeat the purpose for emergency use and suggested striking a balance between the need for emergency access and security.

- Section (7)(B)(1): Sharon Burnett commented the language should allow staffing by other hospital employees such as radiology personnel and suggested referencing "authorized hospital staff." Neil Schmidt asked if the section would require nursing staff

to be present during cleaning and indicated this issue has been raised by the Joint Commission. Dean Linneman commented the draft review committee did not focus on incorporating Joint Commission standards.

- Section (9): Bert McClary indicated use of the term “outside of the pharmacy” was an error and that the rule was intended to require an inventory and reconciliation of all controlled substances. Christian Tadrus indicated the Board of Pharmacy’s sterile compounding draft distinguishes between finished and unfinished products which may need to be accommodated in the draft.

Further discussion was held regarding the feasibility and appropriateness of requiring monthly inventories/reconciliations. Committee members indicated the monthly requirement may be a significant change for some hospitals and could be burdensome. Neil Schmidt asked about potential impact on smaller hospitals. Bert McClary indicated the monthly inventory was intended as a minimum standard. Committee consensus to table the discussion but to review the monthly inventory language prior to finalizing the Committee’s recommendations.

- Section 12: Discussion was held regarding the impact/feasibility of complying with the notification requirements and the definition of when a risk is deemed significant. Committee members suggested the notifications could be burdensome. Bert McClary indicated the notification requirements are a patient safety issue that should be included in the rule. Tom Glenski suggested adding a prescriber notification requirement and suggested deferring to the FDA on when consumer notification is required. Bert McClary suggested requiring notification to the “authorizing practitioner.” Committee consensus to add a prescriber notification requirement.

- Section 13: Christian Tadrus indicated the term “other pertinent information” is vague and noted the draft language did not require patient identification or the dosage form on the label. Bert McClary commented the rule was intended to address the minimum standard. Dean Linneman asked the Committee to identify rule terms that may require further definition.

- Section 14: Sharon Burnett asked if “medication” included oxygen. Bert McClary suggested the term included any product used for a therapeutic effect. Sharon Burnett suggested allowing hospitals to define “medication” in their policies and procedures. James Gray indicated drafting a comprehensive definition would be difficult. Neil Schmidt suggested referencing legend and non-legend drugs or prescription and over-the-counter products. Further discussion was held; no recommended changes suggested.

- Section 15: Discussion was held regarding whether the DHSS rule should incorporate 797, reference the Board’s rules or include a combination of both. Sharon Burnett suggested referencing the Board’s rules if they require USP 797 compliance or if the Board’s rules are consistent with or equivalent/superior to USP 797. Kimberly Grinston reported the Board is still reviewing its sterile compounding rule and that it is unclear how/if the rules will incorporate USP 797. Bert McClary suggested that the Board coordinate with DHSS to provide sterile compounding training for DHSS inspectors. Committee consensus to make no recommended changes at this time but to review the sterile compounding provisions of the DHSS rule after the Board’s sterile compounding rule and USP 797 have been finalized.

- Section 16: Bert McClary indicated this section was discussed in DHSS' environmental services rule review meetings and that the consensus from the environmental review group was to reference a multidisciplinary team. James Gray suggested the section should allow participation by the pharmacy services director or his/her designee. Discussion was held regarding referencing USP Chapter 800 after it becomes official. Committee consensus to add the reference to designee as suggested.

- Section 17: Discussion was held regarding the mandated consultation with a pharmacist given the potential limited involvement of pharmacist with radiopharmaceuticals. No changes were recommended to the draft language.

- Section 18: Discussion was held regarding changing "medication profile" to "medication record." Greg Teale suggested changing "under the control of a practitioner" to "under the supervision of a practitioner" in subsection 2(C)3. Consensus to change the language as suggested.

- Section 19: Greg Teale suggested broadening the language to allow technician-check-technician programs if deemed appropriate in the future. Christian Tadrus suggested the labeling language should be consistent with CMS requirements. Greg Teale asked if the Board of Pharmacy allows pharmacies to accept medication dispensed to the patient. Tom Glenski indicated the Board has previously allowed the practice but commented the medication cannot be further manipulated by the pharmacy.

James Gray asked about the process of "white bagging" or "brown bagging" patient medications and indicated some insurance companies may be requiring white bagging for specialty drugs. Tom Glenski reported the Board allows the practice for hospitals although the Board does not have jurisdiction over what happens once the medication is received. Bert McClary suggested it is in the best interest of the patient to allow the pharmacy to receive and manipulate patient medications. However, Christian Tadrus indicated the practice is not allowed in a community setting for patient safety reasons and commented patient safety standards should not be lowered based on monetary concerns. James Gray indicated the issue of "white bagging"/"brown bagging" may be an issue for pharmacy assistance programs that require patient specific medication to be shipped to the pharmacy. Tom Glenski indicated the issue of "white bagging"/"brown bagging" prescriptions should be addressed in writing at some point. No changes were recommended to the draft language.

- Section 20: James Gray questioned how hospitals would define or enforce the training requirement. Committee consensus to delete the word "trained."

- Section 22: Discussion was held regarding other hospital staff that may be used to inspect medication storage areas. Committee consensus to recommend keeping the deleted language that authorizes use of a designee.

- Section 26: Christian Tadrus commented the language is broad and may open the door for potential abuse by entities who may dispense a full course of therapy for financial reasons. James Gray commented hospitals would be financially discouraged from abusing the allowance because it may result in uncompensated care. Christian commented he is attending the meeting as a Board member and not as an MPA representative.

- Section 27: James Gray asked if the section was still necessary given the recent legislative changes to § 338.165.6, RSMo. Committee consensus to retain the language as drafted but to include a reference to § 338.165.

- Section 30: James Gray asked if the language should address or allow a system wide P&T committee. Sharon Burnett suggested referencing the “medical governance” committee. Daniel Good and Bert McClary commented the current language does not restrict the use of either committee. Sharon Burnett asked if the language should clarify if a pharmacist can serve as pharmacy director for more than one hospital. Bert McClary commented the draft does not prohibit the practice. No recommended changes.

- Section 33: Bert McClary asked if subsection (C) is necessary given the Board’s medication therapy services (MTS) rules and the Board’s jurisdiction over MTS. James Gray commented that the Board’s position on the applicability of its current MTS rules to hospital pharmacy is unclear. Committee consensus to strike subsection (C) given the Board’s rules.

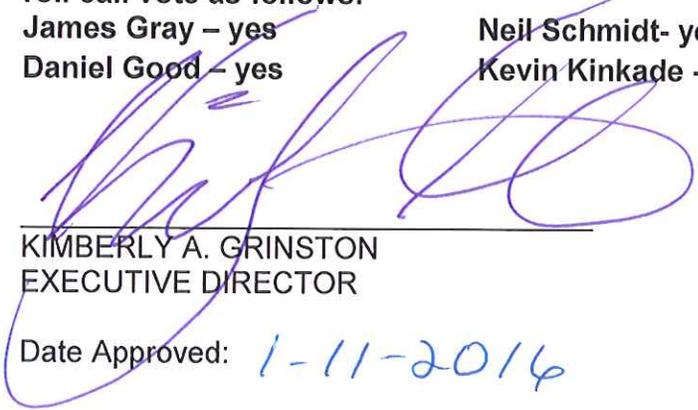
Due to time constraints, the committee agreed by consensus to review the remaining portions of the draft DHSS rule via conference call on December 15, 2015, from approximately 9:00 to 11:00 a.m.

**Agenda Item # 4:** Sharon Burnett introduced Daniel Landon, Senior Vice President of Governmental Relations for MHA. Mr. Landon discussed the possible elimination of the pharmacy carve out from Medicaid. Christian Tadrus commented the pharmacy carve out has been successful and that Missouri would be going backwards in regards to patient care/access in rural communities.

**MOTION TO ADJOURN**

At approximately 3:02 p.m., Daniel Good made a motion, seconded by James Gray, to adjourn the November 6, 2015, meeting. The motion passed 4:0:0:1 with roll call vote as follows:

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



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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

Date Approved: 1-11-2016

Title 19—DEPARTMENT OF HEALTH AND  
SENIOR SERVICES  
Division 30—Division of Regulation and Licensure  
Chapter 20—Hospitals

PROPOSED AMENDMENT

**19 CSR 30-20.100 Pharmacy Services and Medication Management** [*in Hospitals*]. The department is amending the title of the rule and the Purpose statement; deleting sections (8), (12), (20), (21), (34), (35), and (40) and renumbering thereafter; adding new sections (16), (27) and (28); and amending sections (1), (2), (3), (5), (6), (7), (33), (36) through (39), and the new sections (9) through (26), (29) and (32).

*PURPOSE: This amendment updates language throughout and places additional policy and procedure development requirements regarding: pharmacy director responsibilities; pharmacy technician personnel training records; physician review of orders and patient medication profile; medication disposal and recall procedures; and safe handling of compounded and hazardous medication. This amendment also clarifies the requirements associated with policy and procedures related to medication storage and distribution systems, inventory schedules, and medication administration to hospital patients.*

*PURPOSE: This rule establishes the requirements for pharmacy services and medication management in a hospital to ensure optimal selection, safe use, and security of medications.*

(1) Pharmacy services shall be identified and integrated within the total hospital organizational plan. Pharmacy services shall be directed by a **qualified pharmacist** who is currently licensed in Missouri [*and qualified by education and experience*]. **The director of pharmacy services shall be responsible for development, oversight, and evaluation of pharmacy services. Services shall be provided in accordance with state and federal law and according to accepted standards of practice that ensure optimal selection and use of medications.** The director of pharmacy services shall be responsible for the provision of all services required in [*subsection (4)(G) of*] this rule and shall be a participant in all decisions made by pharmacy services or committees regarding the use of medications. With the assistance of medical, nursing and administrative staff, the director of pharmacy services shall develop [*standards*] **policies and procedures for the selection, acquisition, storage, security, distribution, [*and*] safe and effective use, and disposal of medications throughout the hospital. Policies and procedures related to medication management shall be approved by the medical staff and shall include, but not be limited to;**

- (A) Evaluating, selecting, and acquiring medications;
- (B) Access to and security of the pharmacy and all other medication storage areas;
- (C) Loss, diversion, abuse or misuse of controlled substances;
- (D) Inspecting medication storage areas;
- (E) Compounding, labeling, and repackaging of sterile and non-sterile medications;
- (F) Hazardous medications;
- (G) Investigational medications;
- (H) Sample medications;

- (I) Medications subject to recall;
- (J) Patient medication orders;
- (K) Variable time and/or frequency medication orders;
- (L) Administering medications;
- (M) Bedside medications;
- (N) Medications in possession of the patient at the time of admission;
- (O) Disposal of medications and medication waste;
- (P) Reporting medication product problems; and
- (Q) Providing medications for use outside the hospital.

(2) *[Additional]* Sufficient professional and supportive personnel shall be available *[for]* to ensure required services are provided, including, pharmacists and intern pharmacists licensed with the Missouri Board of Pharmacy. ~~Pharmacists and pharmacist interns shall be currently licensed in Missouri~~ *[and all personnel shall possess the education and training necessary for their responsibilities]*.

(3) *[Support pharmacy personnel]* Pharmacy technicians shall work under the supervision of a pharmacist and shall not be assigned duties that by law must be performed by a pharmacist. Interpreting medication orders, selecting, compounding, packaging, labeling and the dispensing of medications by pharmacy *[staff]* technicians shall be performed under the supervision of a pharmacist. Interpretation of medication orders by *[support personnel]* pharmacy technicians shall be limited to order processing and shall not be of a clinical nature. **There shall be evidence of the education, training, experience, and demonstrated competency for all duties assigned in the pharmacy technicians' personnel records.**

(5) Space, equipment and supplies shall be available according to the scope of pharmacy services provided. Office or other work space shall be available for administrative, clerical, clinical and other professional services provided. All areas shall *[meet standards to]* maintain the safety of personnel and the security and stability of medications stored, handled and dispensed.

(6) The pharmacy and its medication storage areas shall have proper conditions of sanitation, temperature, light, moisture, ventilation, *[and]* segregation, and security. Refrigerated medication shall be stored separate from food and other substances. The pharmacy and its medication storage area shall be locked and accessible only to authorized pharmacy and *[supervisory]* designated nursing personnel according to section (20) of this rule. *[The director of pharmacy services, in conjunction with nursing and administration, shall be responsible for the authorization of access to the pharmacy by supervisory nursing personnel to obtain doses for administering when pharmacy services are unavailable.]*

(7) Medication storage areas outside of the pharmacy shall have proper conditions of sanitation, temperature, light, moisture, ventilation, *[and]* segregation and security.

(A) Refrigerated medications shall be stored in a *[sealed compartment]* separate *[from food and laboratory materials]* refrigerator. **The director of pharmacy may approve storage of additional non-food items.**

(B) Medication storage areas, including refrigerators, shall be accessible only to authorized personnel and locked *[when appropriate]* or secure.

1. Medication storage in patient care areas shall be considered secure if located within a locked storage compartment or within a separate closed room in an area that is staffed by ~~nursing personnel~~ **authorized hospital personnel** at all times.

2. Non-controlled substance medications may be stored at the patient's bedside according to hospital policy.

3. Single doses of controlled substances may be stored in a device designed to be kept in the patient's possession for the purpose of oral patient controlled analgesia.

(8) *[The evaluation, selection, source of supply and acquisition of medications shall occur according to the hospital's policies and procedures. Medications and supplies needed on an emergency basis and necessary medications not included in the hospital formulary shall be acquired according to the hospital's policies and procedures.]*

(9) Records shall be maintained of medication transactions, including: acquisition, compounding, repackaging, dispensing or other distribution, administration and controlled substance disposal. Persons involved in compounding, repackaging, dispensing, administration and controlled substance disposal shall be identified and the records shall be retrievable. Retention time for records of bulk compounding, repackaging, administration and all controlled substance transactions shall be a minimum of two (2) years. Retention time for records of dispensing and extemporaneous compounding, including sterile medications, shall be a minimum of six (6) months.

*[(10) Security and record keeping procedures in all areas]* (9) The director of pharmacy services shall ensure the accountability of all controlled substances *[shall address accountability for and other medications subject to theft and abuse and]*. Security and recordkeeping shall be in compliance with *[19 CSR 30-1.030(3)]* applicable provisions of 19 CSR 30-1. Inventories of *[Schedule II]* controlled substances ~~outside the pharmacy~~ shall be *[routinely]* reconciled *[.]* as follows:

(A) When controlled substances outside of the pharmacy are stored in an automated dispensing system all schedules shall be reconciled at least monthly;

(B) When controlled substances outside of the pharmacy are not stored in an automated dispensing system, inventories of Schedule II controlled substances shall be reconciled at each shift change and *[Inventories]* inventories of Schedule III-V controlled substances *[outside of the pharmacy]* shall be *[routinely]* reconciled *[. Records shall be maintained so that inventories of Schedule III-V controlled substances in the pharmacy shall be reconcilable.]* at least daily; and

(C) Inventories of controlled substances in the pharmacy shall be reconciled at least monthly.

Comment [GK1]: The Advisory Committee agreed to review the 30-day requirement again on the December call.

*[(11)]* (10) Controlled *[substance storage areas in the pharmacy]* substances shall be *[separately]* stored in locked *[and]* compartments separate from non-controlled substances. Controlled substances in the pharmacy shall be accessible only to authorized pharmacy staff. *[Reserve supplies of all controlled substances in the pharmacy shall be locked.]* Controlled *[substance storage areas]* substances outside the pharmacy shall be *[separately locked and]* accessible only to persons authorized to administer *[them]* controlled substances and to authorized pharmacy staff.

[(12) Authorization of access to controlled substance storage areas outside of the pharmacy, shall be established by the director of pharmacy services in conjunction with nursing and administration. The distribution and accountability of keys, magnetic cards, electronic codes or other mechanical and electronic devices that allow access to such areas shall occur according to the hospital's policies and procedures.]

[(13)] (11) All variances, discrepancies, inconsistencies or non-compliance involving controlled substances---including inventory, audits, security, record keeping, administration, and disposal---shall be reported to the director of pharmacy services for review and investigation. [Loss, diversion, abuse or misuse of medications shall be reported to the director of pharmacy services, administration, and local, state and federal authorities as appropriate.]

[(14) The provision of pharmacy services in the event of a disaster, removal from use of medications] (12) Medications subject to [product] recall [and reporting of manufacturer drug problems shall occur according to the hospital's policies and procedures] shall be handled through a medication recall program that includes removal of the product from patient care and inventory sites, quarantine of the recalled product and maintenance of records. Where the risk of harm is significant, patients receiving the medication and the prescriber shall be notified.

[(15)] (13) Compounding and repackaging of sterile and non-sterile medications in the pharmacy shall be [done by pharmacy personnel] performed under the supervision of a pharmacist. [Those] Compounded medications shall be labeled with the medication name[,]; strength[,]; lot number, as appropriate; [expiration] beyond use date; and other pertinent information. [Record keeping] Records shall be maintained and quality control, including end-product testing, shall be performed when appropriate [,shall occur according to the hospital's policies and procedures].

[(16)] (14) [Compounding, repackaging or relabeling of] The director of pharmacy services shall determine when non-pharmacy personnel may compound, repackage, or re-label sterile and non-sterile medications [by non-pharmacy personnel shall occur according to the hospital's policies and procedures. Medications] Except in approved circumstances, medications compounded by non-pharmacy personnel shall be administered routinely by the person who prepared them[, ] and preparation shall occur just prior to administration [except in circumstances approved by the director of pharmacy, nursing and administration. Compounded sterile medications for parenteral administration prepared by non-pharmacy personnel shall not be administered beyond twenty-four (24) hours of preparation.] Labeling shall include the patient's name[, where] when appropriate, medication name, strength, beyond use date when appropriate, identity of the person preparing and other pertinent information.

[(17)] (15) Compounded sterile medications shall be [routinely] prepared [in a suitably segregated area in a Class 100 environment by pharmacy personnel. Preparation by nonpharmacy personnel shall occur only in specific areas or in situations when immediate preparation is necessary and pharmacy personnel are unavailable and shall occur according to policies and procedures. All compounded cytotoxic/hazardous medications shall be prepared in

*a suitably segregated area in a Class II biological safety cabinet or vertical airflow hood. The preparation, handling, administration and disposal of sterile or cytotoxic/hazardous medications shall occur according to policies and procedures including: orientation and training of personnel, aseptic technique, equipment, operating requirements, environmental considerations, attire, preparation of parenteral medications, preparation of cytotoxic/hazardous medications, access to emergency spill supplies, special procedures/products, sterilization, extemporaneous preparations and quality control.*], handled, administered and disposed of according to sections (17) and (28) of this rule and as follows:

(A) The director of pharmacy services shall ensure compliance with *USP 31, General Chapter <797> Pharmaceutical Compounding—Sterile Preparations, revised June 2008, published by The United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852.*

(B) Compounded sterile medications shall be prepared in the pharmacy and only by pharmacy personnel except as follows:

1. When prepared for immediate use as defined by *USP 31, General Chapter <797> Pharmaceutical Compounding—Sterile Preparations, revised June 2008*, which is incorporated by reference in this rule and is published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852. This rule does not incorporate any subsequent amendments or additions.

2. When prepared in specific areas or situations when immediate preparation is necessary and pharmacy services are not available, and only by persons who have demonstrated competency in preparation of compounded sterile medications;

(C) Non-pharmacy personnel using a ~~clean air workbench or isolator~~ primary engineering control shall be trained in proper techniques of use.

(16) For hazardous medications, a multidisciplinary team, including the director of pharmacy services or his or her designee, shall ensure appropriate procedures for identification of hazardous sterile and non-sterile medications, training of personnel, storage and handling, facilities, equipment, apparel, preparation, packaging, labeling, transport and handling outside the pharmacy, administering, cleanup of spills, and disposal of medication waste and contaminated materials.

[(18)] (17) Radiopharmaceuticals shall be acquired, stored, handled, prepared, packaged, labeled, distributed, administered and disposed of [*according to the hospital's policies and procedures and*] only by or under the supervision of [*personnel who are certified by the*] a pharmacist or physician who is a Nuclear Regulatory Commission (NRC) authorized user. The NRC authorized supervising pharmacist or physician shall consult with the director of pharmacy to ensure that radiopharmaceuticals are used consistent with the provisions of this rule while recognizing the requirements for physically handling radiopharmaceuticals only by NRC authorized personnel.

[(19)] (18) A medication ~~profile~~ record shall be maintained for each patient.

(A) A medication ~~profile~~ record shall be maintained [*and reviewed*] by the pharmacist, or may be shared by nursing and pharmacy.

1. Entries to a pharmacy medication ~~profile~~ record shall be made only by the prescriber, a pharmacist, or a pharmacy technician. Each entry by a non-pharmacist shall

be reviewed and approved by the pharmacist prior to administering, except as allowed in subsection (C) of this section.

2. Entries to a shared pharmacy and nursing profile medication record shall be made only by the prescriber, a pharmacist, a pharmacy technician or a nurse. Each entry by a non-pharmacist shall be reviewed and approved by the pharmacist. Each entry by a pharmacy technician shall be reviewed and approved by the pharmacist prior to administering.

(B) The pharmacist shall review the medication profile record upon receiving a new medication order prior to dispensing the medication. The pharmacist shall review the original, [prescriber's order or] a direct copy, or a visual image of the order.

(C) The pharmacist shall review a new medication order prior to the administration of the initial dose, except [in an emergency or when] the pharmacist is:

1. In an urgent situation;

2. When the pharmacist is [unavailable, in which case] not available. When the pharmacist is not available the order shall be reviewed within seventy-two (72) hours;

3. When the ordering, preparing, and administration is under the ~~control~~ supervision of a practitioner authorized to order medications.

(D) A pharmacist may review and approve a medication order from a remote location outside of the hospital according to applicable Board of Pharmacy regulations including, but not limited to, 20 CSR 2220-6.055. The remote activity shall ensure the security and confidentiality of patient information.

*[(20) Medications shall be dispensed only upon the order of an authorized prescriber, with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved policy/protocol after an assessment for contraindications, and only dispensed by or under the supervision of the pharmacist.]*

*[(21) All medications dispensed for administration to a specific patient shall be labeled with the patient name, drug name, strength, expiration date and, when applicable, the lot number and other pertinent information.]*

[(22)] (19) The medication distribution system shall provide safety and accountability for all medications, include unit of use and ready to administer packaging, and meet current standards of practice. Distribution systems may include, but are not limited to, traditional unit dose systems and electronic automated systems.

(A) Medications shall be dispensed from the pharmacy only upon the order of an authorized prescriber or upon initiation of a standing order or protocol that includes authority to dispense medication.

(B) Medications shall be dispensed only by or under the supervision of a pharmacist.

(C) All medications for a specific patient shall be dispensed from the pharmacy except when automated dispensing systems are used, when approved floor stock is used or when medications for a specific patient are received from an authorized outside provider.

(D) All medications dispensed for a specific patient shall be labeled with the patient name, medication name, strength, beyond use date and other pertinent information.

(E) Patient medications may be received from an outside contracted medication provider in accordance with applicable Board of Pharmacy regulations and other provisions of this rule.

(F) Patient medications may be received from an authorized outside provider that is not a contracted medication provider. The medications shall:

1. Not be administered unless ordered by an authorized practitioner;
2. Be delivered directly to the pharmacy and not to a patient care area unless the pharmacist is not available; and
3. Be identified, determined suitable for use and documented by the pharmacist, or by an authorized practitioner when the pharmacist is not available, in which case the pharmacist shall also identify the medications within seventy-two (72) hours.

(G) The pharmacy may compound, repackage or re-label medications received from an outside provider, including prescriptions dispensed by a pharmacy, as necessary for proper distribution and administration. Records of compounding, repackaging or relabeling of prescriptions dispensed by a pharmacy shall allow identification of the original prescription.

[(23)] (20) To prevent unnecessary entry to the pharmacy, a locked supply of routinely used medications shall be available for access by authorized personnel when the pharmacist is unavailable. Removal of medications from the pharmacy by ~~trained~~-authorized [*supervisory*] nursing personnel, documentation of medications removed, restricted and unrestricted medication removal, later review of medication orders by the pharmacist, and documented audits of medications [*removal*] removed shall occur according to the hospital's policies and procedures. [*The nurse shall remove only amounts necessary for administering until the pharmacist is available.*]

[(24)] (21) Floor stock medications are medications that are not dispensed from the pharmacy for a specific patient or do not require pharmacist prospective order review/approval. Floor stock medications shall be limited to approved emergency and nonemergency medications [*which are authorized by the director of pharmacy services in conjunction with nursing and administration. The criteria, utilization and monitoring of emergency and non-emergency floor stock medications shall occur according to the hospital's policies and procedures*]. Supplies of emergency medications shall be available in designated areas. Non-emergency floor stock medications shall be available only in limited quantities as determined by the director of pharmacy.

[(25)] (22) All medication storage areas in the hospital shall be inspected at least monthly by a pharmacist or ~~his or her~~ *designee according to the hospital's policies and procedures* ~~pharmacy technician~~. Expired, mislabeled or otherwise unusable medications shall not be available for patient use.

[(26)] (23) The pharmacist shall be responsible for the acquisition, inventory control, dispensing, distribution and related documentation requirements of investigational medications [*according to the hospital's policies and procedures*]. A copy of the investigational protocol shall be available [*in the pharmacy*] to all health care providers who prescribe [*or*], administer,

or dispense investigational medications. The identity of all recipients of investigational medications shall be readily retrievable.

[(27)] (24) Sample medications shall be received and distributed only by the pharmacy [according to the hospital's policies and procedures].

[(28)] (25) Dispensing of medications by the pharmacist [to] for use by patients [who are discharged from the hospital or who are outpatients] outside of the hospital shall be in compliance with [4 CSR 220] Chapter 338, RSMo, and 20 CSR 2220.

[(29) Persons] (26) Medications may be provided to patients for use outside the hospital, by persons other than the pharmacist. [may provide medications to patients leaving the hospital only when prescription services from a pharmacy are not reasonably available. Medications] (A) When the patient is a registered patient of the emergency department or is being discharged from the hospital:

1. Medications shall be provided according to the hospital's policies and procedures, including:

- a. circumstances when medications may be provided[.];
- b. practitioners authorized to order[.];
- c. specific medications [and];
- d. limited quantities[.];
- e. prepackaging and labeling by the pharmacist[.];
- f. final labeling to facilitate correct administration[.];
- g. delivery[.];
- h. counseling; and
- i. a transaction record.

2. Medications shall be labeled with the date, patient's name, prescriber's name, name and address of the hospital, exact medication name and strength, instructions for use and other pertinent information;

3. Medications may be provided only when prescription services from a pharmacy are not reasonably available. Reasonably available includes a pharmacist on duty in the hospital or a community pharmacy within a reasonable distance of the hospital;

4. The medication provided shall be limited to urgently needed treatment as determined by the hospital's policy and procedures;

5. The quantity of medication provided shall be limited to the amount necessary until pharmacy services are available;

6. The provisions of paragraph (A)3 and paragraph (A)5 of this subsection shall not apply when the patient is being treated for an acute condition and it is believed that the immediate health and welfare of the patient and/or the community are in jeopardy. The quantity limit may be extended to provide single-course therapy; and

7. Final labeling, delivery and counseling shall be performed by the prescriber or a registered nurse, except that final labeling and delivery may be performed by an automated dispensing system.

(B) Automated dispensing systems may be used in accordance with all requirements of this section.

1. When the automated dispensing system is controlled by the prescriber it may be used only during times when no pharmacy services are reasonably available, except as allowed in paragraph (A)6 of this section.

2. When the automated dispensing system is controlled by the pharmacy according to regulations of the Missouri Board of Pharmacy, including, but not limited to 20 CSR 2220-2.900, it may be used at all times the pharmacist is on duty.

(C) Medications in multidose containers that were administered to or used for the patient during the patient's hospital stay may be sent with the patient at discharge when so ordered by an authorized practitioner.

1. Examples of multidose medication containers include, but are not limited to, inhalers, ointments, creams, medications requiring the original container for dispensing, insulin pens, eye drops, ear drops and infusions that are currently connected to the patient's infusion device.

2. Medications shall be labeled with the date, patient's name, prescriber's name, name and address of the hospital, exact medication name and strength, instructions for use and other pertinent information.

3. Labeling shall be performed by a pharmacist, prescriber, or registered nurse.

4. Labeled instructions for use may refer to specific written instructions provided by a nurse at the time of discharge.

5. Controlled substances shall not be sent with the patient, except that controlled substance infusions currently connected to the patient's infusion device may be sent as follows:

(a) The medication is necessary for administration during transport of the patient;

(b) The quantity of controlled substance sent is documented in the patient's medical record by the person sending the medication; and

(c) The pharmacy is notified that the medication was sent with the patient.

(27) Medications may be distributed from the pharmacy to locations outside the primary hospital facility under the same procedures used for distribution within the primary hospital facility when the remote location is part of the hospital licensed premises. Except as otherwise authorized by section 338.165.6, RSMo, other distributions to locations outside the hospital shall be according to Missouri Board of Pharmacy drug distribution requirements under 20 CSR 2220-5.020. All controlled substances shall be distributed according to state and federal controlled substance law.

(28) Disposal of medication waste shall be according to 19 CSR 30-20.114 Environmental Waste Management and Support Services.

(A) Medications shall be returned to the pharmacy for disposal except single doses that may be disposed of by authorized staff at the time of administration, infectious and hazardous medications and radiopharmaceuticals.

(B) Disposal of controlled substances shall be according to 19 CSR 30-1.078.

[(30)] (29) Current medication information resources shall be *[maintained]* accessible in the pharmacy and patient care areas. The pharmacist shall provide medication information to the hospital staff as requested.

~~[(31)]~~ (30) The director of pharmacy services or his or her pharmacist designee shall be an active member of the pharmacy and therapeutics committee or its equivalent, which shall advise the medical staff on all medication matters. A formulary shall be established which includes medications based on an objective evaluation of their relative therapeutic merits, safety and cost and shall be reviewed and revised on a continual basis.

(31) A medication use evaluation program shall be established which evaluates the use of selected medications to ensure that they are used appropriately, safely and effectively. Follow-up educational information shall be provided and appropriate interventions implemented if needed in response to evaluation findings.

(32) The pharmacist shall be available to ~~[participate]~~ **consult** with medical and nursing staff ~~[regarding decisions about]~~ **to ensure appropriate** medication use for individual patients, including **but not limited to:** ~~[not to use medication therapy;]~~ medication selection, dosages, routes and methods of administration; medication therapy monitoring; provision of medication-related information; and counseling to individual patients. ~~[The pharmacist or designee shall personally offer to provide medication counseling when discharge or outpatient prescriptions are filled. The pharmacist shall provide requested counseling.]~~

(33) ~~[Medication orders]~~ Medications shall be ~~[initiated or modified]~~ **ordered** only by practitioners who have independent statutory authority to prescribe or who are ~~[legally given authority]~~ **authorized to order medications by their professional licensing agency as provided by state law.** ~~[That authority may be given through an arrangement with a practitioner who has independent statutory authority to prescribe and who is a medical staff member. The]~~

**(A) Authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law. Such authority [may include collaborative practice agreements, protocols or standing orders and] shall not exceed the [practitioner's] scope of practice[. Practitioners given this authority] of the non-physician practitioner. The hospital shall grant appropriate privileges to such non-physician practitioners.**

**(B) Persons who are not hospital employees and who are granted authority to order medications through non-hospital based agreements shall be approved through the hospital credentialing process[. When hospital-based agreements, protocols or standing orders are used, they shall be approved by the pharmacy and therapeutics or equivalent committee] and granted appropriate privileges.**

~~(C) Pharmacist medication therapy services protocols shall:~~

- ~~1. Be authorized pursuant to a document granting hospital privileges to the pharmacist which is signed by the pharmacist;~~
- ~~2. Include the minimum education, training and other qualifications that must be met by the pharmacist; and~~
- ~~3. Be approved by the medical staff.~~

(34) *[All medication orders shall be written in the medical record and signed by the ordering practitioner with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician approved hospital policy/protocol after an assessment for contraindications. When medication therapy is based on a protocol or standing order and a specific medication order is not written, a signed copy of the protocol or of an abbreviated protocol containing the medication order parameters or of the standing order shall be placed in the medical record with the exception of physician approved policies/protocols for the administration of influenza and pneumococcal polysaccharide vaccines after an assessment for contraindications. The assessment for contraindications shall be dated and signed by the registered nurse performing the assessment and placed in the medical record. Telephone or verbal orders shall be accepted only by authorized staff, immediately written and identified as such in the medical record and signed by the ordering practitioner within a time frame defined by the medical staff.]* Hospitals may use pre-printed and electronic standing orders, order sets and protocols for patient medication orders that are authorized to be initiated prior to receiving a patient medication order from an authorized practitioner.

(A) The hospital shall:

1. Establish that such orders and protocols have been reviewed and approved by the medical staff in consultation with the hospital's nursing and pharmacy leadership;

2. Demonstrate that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

3. Ensure that the periodic and regular review of such orders and protocols is conducted by the medical staff, in consultation with the hospital's nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols; and

4. Ensure that such orders and protocols are dated, timed and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient and authorized to write orders by hospital policy in accordance with state law.

(B) Such orders and protocols:

1. Shall describe the clinical conditions under which the order or protocol may be initiated;

2. Shall include the qualifications and/or description of persons who are authorized to initiate the order or protocol within their scope of practice;

3. Shall include the patient care areas and/or type of patients where the order or protocol may be initiated; and

4. Shall be readily retrievable by all persons authorized to order or initiate the order or protocol.

(35) *[Medication orders shall be written according to policies and procedures and those written by persons who do not have independent statutory authority to prescribe shall be included in the quality improvement program.]* With the exception of approved standing orders and protocols, and approved vaccines which may be administered according to policy of the medical staff after an assessment of contraindications, medications shall be administered only upon the order of a person authorized to prescribe or order medications.

(A) All medication orders shall be entered in the medical record by individuals authorized to do so by hospital policy.

**(B) Medication orders shall be signed by the ordering practitioner or authenticated by another practitioner who is responsible for the care of the patient as authorized by state or federal law.**

**(C) Medication orders shall include the medication name, dose, frequency, route of administration, date, and time. The facility shall have a policy for orders with variable doses or frequencies, including the clinical indication for use of the medication.**

**(D) Verbal orders shall be:**

**1. Discouraged and used only when it is impossible or impractical to write the order or enter it electronically without delaying treatment;**

**2. Received only by persons who are authorized by the medical staff and authorized to administer or dispense the ordered medications within their scope of practice;**

**3. Immediately entered, dated, timed, signed and identified as such in the medical record by the receiver;**

**4. Received using a read back procedure; and**

**5. Authenticated by an authorized practitioner within a time frame defined by the medical staff.**

**(E) Prospective medication orders documented or transcribed by persons who do not have authority to administer medications shall be authenticated by an ordering practitioner prior to being initiated.**

(36) Automatic stop orders for all medications shall be established and shall include a procedure to notify the prescriber of an impending stop order. A maximum stop order shall be effective for all medications which do not have a shorter stop order. *[Automatic stop orders are not required when the pharmacist continuously monitors medications to ensure that they are not inappropriately continued.]*

(37) Medications shall be administered only by *[persons]* practitioners who have statutory authority to administer or persons who *[have]* are authorized by the medical staff and meet the following:

**(A) Are at least 18 years of age;**

**(B) Have a high school diploma or equivalent;**

**(C) Have been trained in each *[pharmacological category of]* medication they administer, and administration shall be limited to the scope of their practice; and**

**(D) Persons who do not have statutory authority to administer shall complete a training program approved by the hospital that includes:**

**1. An introduction to human body systems and the effects of medications on them;**

**2. The pharmacology of each drug to be administered, including dosing, interactions, adverse effects, allergies, incompatibilities and contraindications;**

**3. Patient assessment and monitoring;**

**4. Administration routes and techniques, including aseptic and parenteral administration techniques when parenteral medications will be administered;**

**5. Cardiopulmonary resuscitation;**

**6. Acquisition, storing, record keeping and security; and**

**7. Education and clinical training that includes a written and practical examination to demonstrate competency.**

(E) Persons who do not have statutory authority to administer medications shall not administer parenteral medications, controlled substances or medications that require professional assessment by a licensed practitioner at the time of administration unless a practitioner who has statutory authority to administer is immediately available at the time of administration.

(F) *[A person who has statutory authority to administer shall be readily available at the time of administration. Training for persons who do not have statutory authority to administer shall be documented and administration]* Administration by *[those]* persons who do not have statutory authority to administer shall be included in the quality improvement program. *[Medications shall be administered only upon the order of a person authorized to prescribe or order medications. Administration by all persons shall occur according to the hospital's policies and procedures.]*

(G) Health professions students in approved training programs may administer medications under the supervision of their instructors.

(H) Each medication administered shall be documented in the patient's medical record by the person who administered the medication.

(I) Medications shall be self-administered or administered by a patient's representative only upon the order of the prescriber. A nurse shall confirm that administration has occurred and shall document such in the patient's medical record.

(38) Medications *[brought to the hospital by patients]* in the possession of the patient at time of admission shall be *[handled according to policies and procedures]* given to the patient's representative unless there is an identified need to retain them.

(A) Medications that are not given to the patient's representative and that are not to be administered shall be documented, sealed and stored in a locked area accessible only to individuals authorized to access medications.

(B) Controlled substances

1. Shall be inventoried at a minimum upon admission and discharge by a person who is authorized to administer controlled substances or by authorized pharmacy personnel and a copy of each inventory shall be provided to the pharmacy;
2. Shall be security sealed and stored in a locked area accessible only to individuals authorized to administer controlled substances or to authorized pharmacy personnel; and
3. Inventory at the time of discharge shall include a receipt signature of the patient or the patient's representative.

(C) *[They]* Medications shall not be administered unless so ordered by the prescriber and positively identified, determined suitable for administration, and documented by the pharmacist, or by the prescriber when the pharmacist is not available, in which case the pharmacist shall also identify the medications within seventy-two (72) hours.

(D) Medications in the legal possession of the patient shall be returned to the patient or the patient's representative at the time of discharge except when the patient has expired. When medications are not returned to the patient or the patient's representative, they shall be transferred to the pharmacy, documented and destroyed. Controlled substances shall be inventoried and destroyed by two (2) authorized pharmacy personnel.

(39) *[Medications shall be self-administered or administered by a responsible party only upon the order of the prescriber and according to policies and procedures.]* The hospital shall implement a medication safety program to prevent adverse medication events, including medication errors, adverse medication reactions and medication incompatibilities. The program shall:

(A) Be a multidisciplinary program including, but not limited to, the medical staff, pharmacy, nursing and administration;

(B) Provide a procedure to investigate, review, respond and report adverse medication events to the prescriber, the pharmacy, appropriate managers and the hospital's quality assessment and performance improvement program; and

(C) Educate staff about identifying and reporting adverse medication events and their prevention.

*[(40) Medication incidents, including medication errors shall be reported to the prescriber and the appropriate manager. Medication incidents shall be reported to the appropriate committee. Adverse medication reactions shall be reported to the prescriber and the director of the pharmacy services. The medication administered and medication reaction shall be recorded in the patient's medical record. Adverse medication reactions shall be reviewed by the pharmacy and therapeutics committee, and other medical or administrative committees when appropriate.]*

*AUTHORITY: sections [192.006 and] 197.080[, RSMo 2000] and 197.154, RSMo Supp. [2007] 2014.\* This rule previously filed as 19 CSR 30-20.021(3)(G). Original rule filed June 27, 2007, effective Feb. 29, 2008. \*Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

*PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) annually.*

*PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.*

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed amendment with the Missouri Department of Health and Senior Services, Division of Regulation and Licensure, Jeanne Serra, Division Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.*