OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

October 12, 2017
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, Missouri 65109

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
Greg Teale, R.Ph., Member
Daniel Good, R.Ph., Member
James Gray, R.Ph., Member
Colby Grove, R.Ph., Member
Kevin Kinkade, R.Ph., Member
Bert McClary, R.Ph., Member
David Wolfrath, R.Ph., Member

Staff Present
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector
Christa Nilges, Senior Office Support Assistant
Kathie Thomas (Missouri Dept. of Health and Senior Services)

Others Present
Nathan Hansen, R.Ph, Truman Medical Center

Chairman Teale opened the meeting at approximately 10:05 a.m.; roll-call was taken. Introductions of attendees were made.

Agenda Item # 2 (Board of Pharmacy Updates): Kimberly Grinston reported the Governor’s office did not approve the Board’s pharmacy technician legislative proposal for the 2018 session. Ms. Grinston suggested the proposal may have been viewed as an expansion of regulation which is contrary to the Governor’s goal to reduce unnecessary/burdensome regulation. Committee discussion held. Daniel Good and Greg Teale reported the Missouri Hospital Association (MHA) is preparing draft language relating to clinical pharmacy technicians that is not ready for public circulation at this time; Committee comments would be welcomed after the draft is finalized.
Agenda Item # 3 (Department of Health Updates): Kathie Thomas (DHSS Bureau of Hospital Standards) reported she is attending on behalf of Director Richard Grindstaff who was unable to attend. Ms. Thomas provided the following DHSS updates:

- DHSS has been intensively working on the Governor's mandated rule review as well as the implementation of HB 50 and SB 501 in conjunction with MHA.
- The hospital pharmacy rules have been generally discussed but no final changes/decisions have been made. Bert McClary asked if the definition of hospital premises has been amended; Ms. Thomas indicated the definition has been slightly revised and approved by MHA. Draft premises language will be circulated once completed.
- DHSS will likely adopt CMS’ Life Safety and other construction codes/requirements. Bert McClary asked about changes for critical access hospitals; Ms. Thomas reported DHSS is not considering additional/separate rules at this time.

Agenda Item # 5 (Review/Crosswalk of Missouri Hospital Regulations & CMS Conditions of Participation): Mr. Teale reported the Committee has been asked to review DHSS’ proposed hospital pharmacy rule (19 CSR 30-20.100) in light of the CMS preemption language included in SB 501. Mr. Teale suggested any rule provision that duplicates or conflicts with CMS requirements may need to be stricken. Committee discussion on the review process/goals; Kimberly Grinston indicated Sarah Willson is the most knowledgeable on this project and will be joining the meeting closer to lunch. Committee consensus to table until Ms. Willson arrives.

AGENDA ITEM # 6 (Future Meeting Dates/Topics) - Committee discussion held; Consensus to meet on November 15, 2017. James Gray reported he will be out of the office from November until mid-December but asked the Committee to proceed with its work. Greg Teale asked for a deadline to submit comments to DHSS; Ms. Thomas stated the internal goal is to have all rule changes to the Department Director before January 1, 2018.

Agenda Item # 5 (Review/Crosswalk of Missouri Hospital Regulations & CMS Conditions of Participation): In the interest of time, Mr. Teale asked if the Committee should begin initial discussions until Ms. Willson arrives. Bert McClary suggested the Committee discuss the philosophy of the rule review and noted that while limited regulation may be preferable some requirements may still be important. Mr. McClary indicated the majority of hospitals are likely compliant with current standards but questioned what level of oversight should be required for poor performers. Mr. Teale stressed the importance of having a pharmacist in charge of medication dispensing/handling. Committee discussion held.

SARAH WILLSON JOINED THE MEETING AT 11:48 P.M.

Additional Committee discussion held on preempted language in DHSS proposed rule 19 CSR 30-20.100. Preliminary committee suggestions for 19 CSR 30-20.100(1) – (19)
are included in Attachment A (proposed deletions/preempted language identified in red). Due to time constraints, the Committee will review 19 CSR 30-20.100 sections (20) – (39) at a future meeting. Committee consensus to finalize suggestions after the rule review is completed.

A motion was made by Kevin Kinkade, seconded by Daniel Good, to adjourn the meeting. Motion passed by unanimous vote.

THE HOSPITAL ADVISORY COMMITTEE ADJOURNED BY CONSENSUS AT 2:48 P.M.

KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

Date Approved: November 14, 2017
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. 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 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 policies and procedures for the selection, acquisition, storage, security, distribution, 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;
(II) 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) **Sufficient** professional and supportive personnel shall be available to ensure required services are provided. Pharmacists and pharmacist interns shall be currently licensed in Missouri.

(3) 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 technicians shall be performed under the supervision of a pharmacist. Interpretation of medication orders by 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 maintain the safety of personnel and the security and stability of medications stored, handled and dispensed.

Strike current 4

(6) The pharmacy and its medication storage areas shall have proper conditions of sanitation, temperature, light, moisture, ventilation, 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 designated nursing personnel according to section (20) of this rule.

(7) Medication storage areas outside of the pharmacy shall have proper conditions of sanitation, temperature, light, moisture, ventilation, segregation and security. (A) Refrigerated medications shall be stored in a separate 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 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 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) 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.

(9) The director of pharmacy services shall ensure the accountability of all controlled substances. Security and recordkeeping shall be in compliance with applicable provisions of 19 CSR 30-1. Inventories of controlled substances outside the pharmacy shall be reconciled as follows:
(A) When controlled substances are stored in an automated dispensing system all schedules shall be reconciled at least monthly;
(B) When controlled substances are not stored in an automated dispensing system, inventories of Schedule II controlled substances shall be reconciled at each shift change and inventories of Schedule III–V controlled substances shall be reconciled at least daily; and
(C) Inventories of controlled substances in the pharmacy shall be reconciled at least monthly.

(10) Controlled substances shall be stored in locked compartments separate from non-controlled substances. Controlled substances in the pharmacy shall be accessible only to authorized pharmacy staff. Controlled substances outside the pharmacy shall be accessible only to persons authorized to administer controlled substances and to authorized pharmacy staff.
(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.

(12) **Medications subject to recall** 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 shall be notified.

(13) Compounding and repackaging of sterile and non-sterile medications in the pharmacy shall be **performed** under the supervision of a pharmacist. **Compounded** medications shall be labeled with the medication name, strength, lot number, as appropriate, beyond use date, and other pertinent information. **Records shall be maintained** and quality control, including end-product testing, shall be performed when appropriate. **Tag 501**.

(14) The director of pharmacy services shall determine when non-pharmacy personnel may compound, repackage, or re-label sterile and non-sterile 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. Labeling shall include the patient’s name when appropriate, medication name, strength, beyond use date when appropriate, identity of the person preparing and other pertinent information. **TAG 405 & 501**

(15) Compounded sterile medications shall be prepared, 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,** 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.

(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 shall be trained in proper techniques of use.**

(16) For hazardous medications, a multidisciplinary team, including the director of pharmacy services, 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.

(17) Radiopharmaceuticals shall be acquired, stored, handled, prepared, packaged, labeled, distributed, administered and disposed of only by or under the supervision of 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.

(18) A medication profile shall be maintained for each patient.
(A) A medication profile shall be maintained by the pharmacist, or may be shared by nursing and pharmacy.
   1. Entries to a pharmacy medication profile 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 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 upon receiving a new medication order prior to dispensing the medication. The pharmacist shall review the original, 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 when the pharmacist is:
   1. In an urgent situation;
   2. When the pharmacist is 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 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.

(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.

[Sections 20 – 39 were not reviewed due to time constraints]
(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 nursing personnel, documentation of medications removed, restricted and unrestricted medication removal, later review of medication orders by the pharmacist, and documented audits of medications removed shall occur according to the hospital’s policies and procedures.

(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. 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.

(22) All medication storage areas in the hospital shall be inspected at least monthly by a pharmacist or pharmacy technician. Expired, mislabeled or otherwise unusable medications shall not be available for patient use.

(23) The pharmacist shall be responsible for the acquisition, inventory control, dispensing, distribution and related documentation requirements of investigational medications. A copy of the investigational protocol shall be available to all health care providers who prescribe, administer, or dispense investigational medications. The identity of all recipients of investigational medications shall be readily retrievable.
Sample medications shall be received and distributed only by the pharmacy.

Dispensing of medications by the pharmacist for use by patients outside of the hospital shall be in compliance with 20 CSR 2220.

Medications may be provided to patients for use outside the hospital, by persons other than the pharmacist. (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. 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.

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

(30) The director of pharmacy services 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 consult with medical and nursing staff to ensure appropriate medication use for individual patients, including but not limited to: medication selection, dosages, routes and methods of administration; medication therapy monitoring; provision of medication-related information; and counseling to individual patients.

(33) Medications shall be ordered only by practitioners who have independent statutory authority to prescribe or who are authorized to order medications by their professional licensing agency as provided by state law.

(A) Authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law. Such authority shall not exceed the scope of practice 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 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) 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) 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.

(37) Medications shall be administered only by practitioners who have statutory authority to administer or persons who 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 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) Administration by persons who do not have statutory authority to administer shall be included in the quality improvement program.

(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 in the possession of the patient at time of admission shall be 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) 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) 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.


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.