Notice is hereby given that the Missouri Board of Pharmacy’s Hospital Advisory Committee will be meeting at 10:00 a.m. on November 14, 2017. A tentative agenda is attached. If any member of the public wishes to attend the meeting by participating in the conference call, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 10:00 a.m. on November 14, 2017.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy’s Hospital Advisory Committee is authorized to close meetings, records and votes pursuant to Section 610.021(1). The Committee may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Please see the attached tentative agenda for this meeting.
TENTATIVE AGENDA

Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

November 14, 2017
10:00 a.m.
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

1. Welcome & Introductions

2. Approval of Minutes
   a. August 7, 2017
   b. October 12, 2017

3. Board of Pharmacy Updates

4. Department of Health Updates

5. Review/Crosswalk of Missouri Hospital Regulations and CMS Conditions of Participation
   a. Bert’s Quick Reference Guide
   b. SB 501
   c. 19 CSR 30-20.100 (w/10-12-17 Committee Changes)
   d. Proposed 19 CSR 30-20.015
   e. 19 CSR 30-20.011
   f. Other rules potentially impacted (e.g., 19 CSR 30-20.080, .086)
   g. Impact on Critical Access Hospitals/ CMS State Operations Manual Appendix W

6. Future Meeting Dates/Topics

7. Public Questions/Comments

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

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

**Staff Present**
Barbara Bilek, Board Member  
Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector  
Katie DeBold, Inspector  
Christa Nilges, Senior Office Support Assistant

**Others Present**
Chairman McClary opened the meeting at approximately 10:06 a.m. and roll-call was taken.

**Agenda Item # 2 (Approval of Minutes):** The March 9, 2017, minutes were presented for approval. A motion was made by Greg Teale, seconded by James Gray, to approve the March 9, 2017, minutes. The motion passed 3:0:0:2 with roll call vote as follows:

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

A motion was made by Greg Teale, seconded by Colby Grove, to approve the May 4, 2017, minutes. James Gray asked to abstain because he was unable to attend the full meeting. The motion passed 2:0:1:2 with roll call vote as follows:

- James Gray – abstain  
- Colby Grove- yes  
- Greg Teale – yes  
- Daniel Good – absent  
- Kevin Kinkade - absent
Agenda Item # 3 (Board of Pharmacy Updates): Kimberly Grinston reported the Board met in the month of July. Ms. Grinston indicated the majority of Board updates overlap with other agenda items and asked to provide updates as those items are discussed.

DANIEL GOOD JOINED THE MEETING AT 10:14 A.M.

Agenda Item # 5 (Department of Health Updates): Ms. Grinston reported Department of Health and Senior Service (DHSS) employees may be unable to attend due to an urgent scheduling conflict.

Agenda Item # 6 (Review of Outstanding Issues): Ms. Grinston reported the proposed Class-B rule and the automated distribution rule are still in the early drafting stages and need to be discussed/reviewed by the Committee. Chairman McClary inquired about the Class-B Guidance Document; Ms. Grinston indicated the office has consulted with DHSS who agreed the Board should delay releasing the guidance document in light of SB 501.

Agenda Item # 7 (Review of 2017 Legislation): The following Committee discussion was held:

- Kimberly Grinston reported the 2017 legislation would authorize pharmacists to dispense Naloxone under a statewide standing order issued by DHSS. Ms. Grinston further reported the Board deems the statutory language to be self-executing. This would allow the statute to become effective without additional rulemaking, however, the Board may consider rule guidance in the future. Committee discussion held on implementation procedures; Ms. Grinston advised additional information will be provided during the Board’s upcoming legislative webinar.

- Sarah Willson reported SB 501 preempts DHSS rules/statutes that duplicate or conflict with CMS’ conditions of participation. Ms. Willson further reported the Missouri Hospital Association will be working with DHSS to review affected statutes/rules; any preempted rule would need to be re-promulgated by July 2018. Committee discussion held. Greg Teale asked if the rule review process would address individuals authorized to administer medication and noted Missouri law prohibits administration of parenteral or controlled medications by some hospital staff. Mr. Teale noted this is problematic in radiology and procedural issues and suggested clarifying DHSS’ statutes/rules to clearly address who can administer medication under a physician’s supervision. Ms. Willson indicated medication administration has not been specifically discussed but suggested reviewing the previously proposed DHSS hospital pharmacy rule at a later Committee meeting. Kimberly Grinston and Bert McClary asked if SB 501 would modify the definition of the hospital premises; Ms. Willson indicated the definition has not been discussed during preliminary SB 501 conversations but agreed to provide updates as they develop.
• Bert McClary reported SB 501 appears to expand the class of individuals eligible for licensure as an assistant physician and also limits medication dispensing by physician assistants.

AGENDA ITEM # 9 (2018 Proposed Legislation): The following Committee discussion was held:
• Mr. McClary reported the previously discussed advancement of pharmacy practice language was not filed during the 2017 legislative session due to more pressing issues being promoted by the Missouri Pharmacy Association. Mr. McClary reported the proposed language would have addressed practice issues such as pharmacist prescribing authority for both controlled and non-controlled medication and implementation of a medication therapy protocol without a prescription order. Mr. McClary suggested finding a legislative partner that is more hospital focused given that fewer community pharmacies may provide medication therapy services. Mr. McClary further reported pharmacist reimbursement is still a pressing issue that may need to be addressed via an insurance statute. James Gray suggested representatives stress the proposed legislation would promote patient access to needed medical services and not just expand pharmacy practice.
• Greg Teale asked if the Board’s pharmacy technician proposal would be submitted in 2018. Kimberly Grinston reported the Board’s proposal is pending approval by the Governor’s office, however, this would not prohibit other entities from presenting legislation. Bert McClary questioned if a comprehensive pharmacy technician proposal would be beyond the Committee’s scope.

AGENDA ITEM # 8 (Strategic Review of Committee Operations)- Chairman McClary asked for input on the Committee’s operations and the Committee’s alignment with statutory goals. Greg Teale noted there are several outstanding issues, such as epinephrine dispensing/administration, Class-B pharmacy rules, automated cabinets, sterile compounding, medication administration, pharmacy technician regulation, DHSS/CMS varying standards and drug returns. Daniel Good suggested additional independent review by Committee members may be helpful; Bert McClary and James Gray noted multiple Committee members were absent. Committee consensus to hold for discussion with the full Committee. Daniel Good suggested gathering input from the Board as well as representative groups.

AGENDA ITEM # 10 (Election of Officer)- Chairman McClary reported he will be resigning as Chairman but not as a member. Mr. McClary noted he has enjoyed chairing the Committee but suggested rotating officers would encourage a diversity of opinion and leadership. Committee discussion held. Mr. McClary asked if the tenure of the Chairman should be limited; Committee members indicated they are comfortable with the current natural attrition but may need to reconsider in the future. Daniel Good nominated Greg Teale as Chairman; Greg Teale accepted the nomination. No other nominations were made. All committee members voted in favor of electing Greg Teale as Chair.
Sarah Willson asked if the HAC’s scope should be expanded to include DHSS issues that may not relate to the Board given the broad range of DHSS pharmacy related topics; Kimberly Grinston indicated this may be a statutory issue but could be discussed with the Board.

A motion was made by James Gray, seconded by Greg Teale, to commend and recognize Chairman McClary for his exemplary work with the inaugural committee. The motion passed by unanimous vote.

**AGENDA ITEM # 13 (Future Meeting Dates/Topics)** Committee discussion held; Committee consensus to meet during the 2\textsuperscript{nd} week of October. Board staff will survey Committee members to determine best available dates.

THE HOSPITAL ADVISORY COMMITTEE ADJOURNED BY CONSENSUS AT 2:20 P.M.

__________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
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:
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;
(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) 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...
(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 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, repackageing 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.
(24) Sample medications shall be received and distributed only by the pharmacy.

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

(26) 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;
   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.
Governing body
0045 45 practitioners eligible for med staff
0050 50 criteria for selection
0064 69 patients under care of physician or other

Quality assessment/performance improvement
0263 170 ongoing, hospital wide, data-driven (includes pharmacy/medication topics)
0286 171 patient safety, medication errors, adverse events

Medical staff
0339 174 med staff may include non-physician practitioners
0341 179 examine credentials, make rec to gov body in accord w/ scope of practice laws
0357 204 bylaws describe qualifications for recommending appt
0363 210 criteria for determining privileges to be granted

Nursing services
0405 221 drugs prepared/admin acc to stds of practice; admin on order of other practitioners
0405 221 drugs admin by nursing or others according to licensing requirements
0406 235 standing orders and protocols meet 482.24(c)(3), tag 0457 p 273
0407 237 verbal orders used infrequently, received by auth persons
0409 239 IV meds admin according to P&P
0410 248 reporting ADRs and med errors
0412 250 P&P for self admin of hospital or patient’s own drugs
0413 255 P&P for self admin of patient’s own drugs

Medical records
0449 267 content describe progress & response to meds
0450 268 entries legible, complete, dated, timed, authenticated written or electronic
0454 271 orders including verbal may be authenticated by another practitioner
0457 273 criteria for standing orders and protocols
0464 282 document evaluations & findings by clinical and other staff
0465 283 document unfavorable reactions to drugs and anesthesia
0467 286 practitioner’s orders, nursing notes, reports of treatment, med records, other
0468 287 discharge summary, follow-up care

Pharmaceutical services
0490 288 meet needs of patients, dir by RPh, med staff resp, may delegate to pharm svcs
0491 290 admin in accord w/ professional principles
0492 293 pharmacist resp for developing, supervising, coordinating all activities
0493 295 adequate number of personnel
0494 296 records of receipt/disposition of all scheduled drugs
0500 298 drugs controlled/distributed in accord w/ standards of practice
0501  301 all compounding, packaging, dispensing under supervision of pharmacist  
0502  302 drugs kept in secure area, locked when appropriate  
0503  314 CII-V locked within secure area  
0504  315 only authorized personnel access to locked areas  
0505  316 outdated, mislabeled, unusable drugs not available for pt use  
0506  318 P&P for removal of drugs when pharmacist not available  
0507  319 automatic stop orders  
0508  320 administration errors, ADRs, incompatibilities reported  
0509  324 abuses and losses of CS reported  
0510  325 drug info available to professional staff  
0511  326 formulary system must be established  

**Physical environment**  
0722  386 maintain adequate facilities  
0724  387 maintain facilities, supplies and equipment at acceptable levels of safety  
0726  398 ventilation, light, temperature—storage for pharmaceuticals  

**Infection control**  
0747  399 sanitary environment; prevention, control and investigation  

**Discharge planning**  
0799  411 discharge plan (includes medication related issues)  

**Anesthesia services**  
1001  476 who may administer  
1004  484 intraoperative record  

**Nuclear medicine services**  
1027  491 personnel (including pharmacists)  
1035  493 preparation, transport, storage, disposal  
1036  495 in-house preparation  

**Respiratory services**  
1160  520 delivery of services (including medications)  
1163  522 practitioners who may order (incl non-physicians; pharmacists—silent)
AN ACT
To repeal sections 191.227, 195.206, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 334.010, 334.036, 334.735, 337.010, 337.025, 338.010, and 345.051, RSMo, and to enact in lieu thereof twenty-four new sections relating to health care, with an effective date for certain sections.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 191.227, 195.206, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 334.010, 334.036, 334.735, 337.010, 337.025, 338.010, and 345.051, RSMo, are repealed and twenty-four new sections enacted in lieu thereof, to be known as sections 191.227, 194.600, 195.205, 195.206, 196.990, 197.005, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 198.053, 324.003, 334.010, 334.036, 334.735, 337.010, 337.025, 338.010, 345.051, 478.004, 487.200, and 1, to read as follows:

191.227. 1. All physicians, chiropractors, hospitals, dentists, and other duly licensed practitioners in this state, herein called "providers", shall, upon written request of a patient, or guardian or legally authorized representative of a patient, furnish a copy of his or her record of that patient's health history and treatment rendered to the person submitting a written request, except that such right shall be limited to access consistent with the patient's condition and sound therapeutic treatment as determined by the provider. Beginning August 28, 1994, such record shall be furnished within a reasonable time of the receipt of the request therefor and upon payment of a fee as provided in this section.

2. Health care providers may condition the furnishing of the patient's health care records to the patient, the patient's authorized representative or any other person or entity authorized by law to obtain or reproduce such records upon payment of a fee for:

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.
exercising reasonable care fails to administer an epinephrine auto-
injector shall be liable for such failure.

8. All basic life support ambulances and stretcher vans operated
in the state shall be equipped with epinephrine auto-injectors and be
staffed by at least one individual trained in the use of epinephrine
auto-injectors.

9. The provisions of this section shall apply in all counties within
the state and any city not within a county.

10. Nothing in this section shall be construed as superseding the
provisions of section 167.630.

197.005. 1. As used in this section, the term "Medicare conditions
of participation" shall mean federal regulatory standards established
under Title XVIII of the Social Security Act and defined in 42 CFR 482,
as amended, for hospitals and 42 CFR 485, as amended, for hospitals
designated as critical access hospitals under 42 U.S.C. Section 1395i-4.

2. To minimize the administrative cost of enforcing and
complying with duplicative regulatory standards, on and after July 1,
2018, compliance with Medicare conditions of participation shall be
deemed to constitute compliance with the standards for hospital
licensure under sections 197.010 to 197.120 and regulations
promulgated thereunder.

3. Nothing in this section shall preclude the department of health
and senior services from promulgating regulations effective on or after
July 1, 2018, to define separate regulatory standards that do not
duplicate or contradict the Medicare conditions of participation, with
specific state statutory authorization to create separate regulatory
standards.

4. Regulations promulgated by the department of health and
senior services to establish and enforce hospital licensure regulations
under this chapter that duplicate or conflict with the Medicare
conditions of participation shall lapse and expire on and after July 1,
2018.

197.040. After ninety days from the date this law becomes effective, no
person or governmental unit, acting severally or jointly with any other person or
governmental unit, shall establish, conduct or maintain a hospital in this state
without a license under this law and section 197.005 issued by the department
of health and senior services.

197.050. Application for a license shall be made to the department of
health and senior services upon forms provided by it and shall contain such
information as the department of health and senior services requires, which may
include affirmative evidence of ability to comply with such reasonable standards,
rules and regulations as are lawfully prescribed hereunder in compliance with
section 197.005. Until June 30, 1989, each application for a license, except
applications from governmental units, shall be accompanied by an annual license
fee of two hundred dollars plus two dollars per bed for the first one hundred beds
and one dollar per bed for each additional bed. Beginning July 1, 1989, each
application for a license, except applications from governmental units, shall be
accompanied by an annual license fee of two hundred fifty dollars plus three
dollars per bed for the first four hundred beds and two dollars per bed for each
additional bed. All license fees shall be paid to the director of revenue and
deposited in the state treasury to the credit of the general revenue fund.

197.070. The department of health and senior services may deny, suspend
or revoke a license in any case in which it finds that there has been a substantial
failure to comply with the requirements established under this law and section
197.005.

197.071. Any person aggrieved by an official action of the department of
health and senior services affecting the licensed status of a person under the
provisions of sections [197.010] 197.005 to 197.120, including the refusal to
grant, the grant, the revocation, the suspension, or the failure to renew a license,
may seek a determination thereon by the administrative hearing commission
pursuant to the provisions of section 621.045, and it shall not be a condition to
such determination that the person aggrieved seek a reconsideration, a rehearing,
or exhaust any other procedure within the department of health and senior
services.

197.080. 1. The department of health and senior services, with the advice
of the state advisory council and pursuant to the provisions of this section,
section 197.005, and chapter 536, shall adopt, amend, promulgate and enforce
such rules, regulations and standards with respect to all hospitals or different
types of hospitals to be licensed hereunder as may be designed to further the
accomplishment of the purposes of this law in promoting safe and adequate
treatment of individuals in hospitals in the interest of public health, safety and
welfare. No rule or portion of a rule promulgated under the authority of sections
197.010 to 197.280 shall become effective unless it has been promulgated
pursuant to the provisions of section 536.024.

2. The department shall review and revise regulations governing hospital
licensure and enforcement to promote hospital and regulatory efficiencies
[and]. The department shall eliminate all duplicative regulations and
inspections by or on behalf of state agencies and the Centers for Medicare and Medicaid Services (CMS). The hospital licensure regulations adopted under this section shall incorporate standards which shall include, but not be limited to, the following:

1. Each citation or finding of a regulatory deficiency shall refer to the specific written regulation, any state associated written interpretive guidance developed by the department and any publicly available, professionally recognized standards of care that are the basis of the citation or finding;

2. Subject to appropriations, the department shall ensure that its hospital licensure regulatory standards are consistent with and do not contradict the CMS Conditions of Participation (COP) and associated interpretive guidance. However, this shall not preclude the department from enforcing standards produced by the department which exceed the federal CMS' COP and associated interpretive guidance, so long as such standards produced by the department promote a higher degree of patient safety and do not contradict the federal CMS' COP and associated interpretive guidance;

3. The department shall establish and publish guidelines for complaint investigation, including but not limited to:
   a. The department's process for reviewing and determining which complaints warrant an on-site investigation based on a preliminary review of available information from the complainant, other appropriate sources, and when not prohibited by CMS, the hospital. For purposes of providing hospitals with information necessary to improve processes and patient care, the number and nature of complaints filed and the recommended actions by the department and, as appropriate CMS, shall be disclosed upon request to hospitals so long as the otherwise confidential identity of the complainant or the patient for whom the complaint was filed is not disclosed;
   b. A departmental investigation of a complaint shall be focused on the specific regulatory standard and departmental written interpretive guidance and publicly available professionally recognized standard of care related to the complaint. During the course of any complaint investigation, the department shall cite any serious and immediate threat discovered that may potentially jeopardize the health and safety of patients;
   c. A hospital shall be provided with a report of all complaints made against the hospital. Such report shall include the nature of the complaint, the date of the complaint, the department conclusions regarding the complaint, the number of investigators and days of investigation resulting from each complaint;

4. Hospitals and hospital personnel shall have the opportunity to
participate in annual continuing training sessions when such training is provided
to state licensure surveyors with prior approval from the department director and
CMS when appropriate. Hospitals and hospital personnel shall assume all costs
associated with facilitating the training sessions and use of curriculum materials,
including but not limited to the location for training, food, and printing costs;
(5) Time lines for the department to provide responses to hospitals
regarding the status and outcome of pending investigations and regulatory
actions and questions about interpretations of regulations shall be identical to,
to the extent practicable, the time lines established for the federal hospital
certification and enforcement system in the CMS State Operations Manual, as
amended. These time lines shall be the guide for the department to
follow. Every reasonable attempt shall be made to meet the time lines. However,
failure to meet the established time lines shall in no way prevent the department
from performing any necessary inspections to ensure the health and safety of
patients.

3. Any rule or portion of a rule, as that term is defined in section 536.010,
that is created under the authority delegated in this section shall become effective
only if it complies with and is subject to all of the provisions of chapter 536 and,
if applicable, section 536.028. This section and chapter 536 are nonseverable and
if any of the powers vested with the general assembly pursuant to chapter 536 to
review, to delay the effective date, or to disapprove and annul a rule are
subsequently held unconstitutional, then the grant of rulemaking authority and
any rule proposed or adopted after August 28, 2013, shall be invalid and void.

197.100. 1. Any provision of chapter 198 and chapter 338 to the contrary
notwithstanding, the department of health and senior services shall have sole
authority, and responsibility for inspection and licensure of hospitals in this state
including, but not limited to, all parts, services, functions, support functions and
activities which contribute directly or indirectly to patient care of any kind
whatsoever. The department of health and senior services shall annually inspect
each licensed hospital and shall make any other inspections and investigations
as it deems necessary for good cause shown. The department of health and senior
services shall accept reports of hospital inspections from or on behalf of
governmental agencies, the joint commission, and the American Osteopathic
Association Healthcare Facilities Accreditation Program, provided the
accreditation inspection was conducted within one year of the date of license
renewal. Prior to granting acceptance of any other accrediting organization
reports in lieu of the required licensure survey, the accrediting organization’s
survey process must be deemed appropriate and found to be comparable to the
whole patient approach to the treatment of substance use disorders.

2. If a drug court or veterans court participant requires treatment for opioid or other substance misuse or dependence, a drug court or veterans court shall not prohibit such participant from participating in and receiving medication-assisted treatment under the care of a physician licensed in this state to practice medicine. A drug court or veterans court participant shall not be required to refrain from using medication-assisted treatment as a term or condition of successful completion of the drug court program.

3. A drug court or veterans court participant assigned to a treatment program for opioid or other substance misuse or dependence shall not be in violation of the terms or conditions of the drug court or veterans court on the basis of his or her participation in medication-assisted treatment under the care of a physician licensed in this state to practice medicine.

487.200. 1. As used in this section, "medication-assisted treatment" means the use of pharmacological medications, in combination with counseling and behavioral therapies, to provide a whole patient approach to the treatment of substance use disorders.

2. If a family court participant requires treatment for opioid or other substance misuse or dependence, a family court shall not prohibit such participant from participating in and receiving medication-assisted treatment under the care of a physician licensed in this state to practice medicine. A family court participant shall not be required to refrain from using medication-assisted treatment as a term or condition of successful completion of the family court program.

3. A family court participant assigned to a treatment program for opioid or other substance misuse or dependence shall not be in violation of the terms or conditions of the family court on the basis of his or her participation in medication-assisted treatment under the care of a physician licensed in this state to practice medicine.

Section 1. The Missouri board of pharmacy, in consultation with the Missouri department of health and senior services, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop a drug take-back program. Such program shall collect and dispose of Schedule II and III controlled substances, as described in section 195.017.

Section B. The enactment of section 197.005 and the repeal and reenactment of sections 197.040, 197.050, 197.070, 197.071, 197.080, and 197.100
3 of this act shall become effective on July 1, 2018.
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:

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.
(24) Sample medications shall be received and distributed only by the pharmacy.

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

(26) 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;
   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.
PROPOSED AMENDMENT

19 CSR 30-20.011 Definitions Relating to Hospitals

PURPOSE: This rule defines terminology used throughout this chapter.

(1) ACLS—The American Heart Association’s advanced cardiac life support program.

(2) Acute care service area—An area of a hospital that provides care primarily for patients with acute diseases or conditions. This does not include care provided in a long-term care unit such as a skilled nursing, swing bed, and intermediate care unit.

(3) Anesthesiologist assistant (AA)—A person who:
   1. Has graduated from an anesthesiologist assistant program accredited by the Medical Association’s Committee on Allied Health Education and Accreditation or by its successor agency;
   2. Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;
   3. Has active certification by the National Commission on Certification of Anesthesiologist Assistants;
   4. Is currently licensed as an anesthesiologist assistant in the state of Missouri; and
   5. Provides health care services delegated by a licensed anesthesiologist.

(4) [(2)] Anesthetizing location—An area or room in which it is intended to administer any flammable or nonflammable inhalation anesthetic agents in the course of examination or treatment.

(5) [(3)] APLS—The American College of Emergency Physician’s advanced pediatric life support program. APLS may be used interchangeably with PALS where required.

(6) [(4)] ATLS—The American College of Surgeon’s advanced trauma life support program.
Authenticate—To prove authorship, for example, by written signature, identifiable initials, rubber stamp [or computer key] or electronic signature. [The use of rubber stamp signatures is acceptable only under the following conditions:

(A) The individual whose signature the rubber stamp represents is the only one who has possession of the stamp and is the only one who uses it; and

(B) The individual places in the administrative office of the hospital, with a copy to the medical records director, a signed statement to the effect that s/he is the only one who has the stamp and is the only one who will use it.]

Biological safety cabinet—A containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Safety Foundation, Standard 49.

Board-certified—[That] A physician that has fulfilled all requirements, has satisfactorily completed all written and oral examinations and has been awarded a board diploma in a specialty field.

Board-eligible [admissible]—[That] A physician that has applied to a specialty board and has received a ruling that s/he has fulfilled the requirements to take the certification examinations. Board certification must be obtained within five (5) years after completion of the residency.

Campus—the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings.

Certified registered nurse anesthetist—[A registered nurse who has graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Educational Programs of Nurse Anesthesia or its predecessor and has been certified or is eligible for certification as a nurse anesthetist by the National Board for Certification and Recertification of Nurse Anesthetists or Council on Certification of Nurse Anesthetists] and is currently licensed to practice professional nursing in Missouri. A person who is currently certified under chapter 335, RSMo, as a Certified Registered Nurse Anesthetist in the State of Missouri.

Chemical Restraint—A drug or medication when it is used as a restriction to manage the patient’s behavior or restrict the patient’s freedom of movement and is not a standard treatment or dosage for the patient’s condition.
Chief executive officer—The individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice president and executive vice president.

Chief operating officer—The individual appointed by the chief executive officer on behalf of the governing body or the individual who is responsible for the management of one (1) hospital in a multi-hospital organization under the direction of the chief executive officer of the organization.

Class II biological safety cabinet—A ventilated cabinet for personnel, product and environmental protection having an open front with inward airflow for personnel protection, high-efficiency-particulate-air (HEPA) filtered laminar airflow for product protection and HEPA-filtered exhausted air for environmental protection.

Class 100 environment—An atmospheric environment which contains less than one hundred (100) particles five-tenths (0.5) microns or larger in diameter per cubic foot of air, according to federal standard 209E.

Credible Allegation – A written or verbal claim or assertion that someone has done something illegal or wrong and is believed to be true. A written or verbal claim or assertion that the hospital has reason to believe is true after a preliminary investigation.

Defined service area—The geographic area served by a defined group of hospitals and emergency services. In areas where there is a community-based emergency medical services diversion plan, the service area(s) defined as the catchment area by the plan will be the defined service area(s). In areas where there is not a community-based emergency medical services diversion plan, the defined service area will be a twenty (20)-mile radius from a hospital.

Dentist—An individual who has received a Doctor of Dental Surgery or Doctor of Dental Medicine degree and is currently licensed under chapter 332, RSMo, to practice dentistry in the State of Missouri.

Department—Missouri Department of Health and Senior Services.

Detailed Investigation – A careful examination of facts regarding any credible allegation or never event that may include but not be limited to: interviews; video surveillance assessment and written statements.
DRAFT

(186) [(28) Qualified] Dietitian—An individual who is currently licensed under chapter 324, RSMo, to practice as a dietitian in the State of Missouri. [registered by the Commission on Dietetic Registration of the American Dietetic Association or who has the documented equivalent in education, training and experience, with evidence of relevant continuing education.]

(197) [(42)] Diversion—A plan to temporarily close a hospital emergency department to ambulance traffic. [This may be due to the emergency department being overwhelmed with significantly critically ill or injured patients, or an overwhelming number of minor emergency patients, to the extent that the hospital is unable to provide quality care or protect the health or welfare of the patients it serves. A diversion also may be implemented if the hospital has resource limitations, such as, no available beds in specialty care units or general acute care, no surgical suites or shortages of equipment or personnel.]

(20) Distant site telemedicine or telehealth entity – A telemedicine or telehealth hospital where the health care provider providing the telemedicine or telehealth service is physically located at the time the telemedicine or telehealth service is provided, a site at which a health care provider is located while providing health care services by means of telemedicine.19

CSR 30-20.080

(18) General Acute Care Hospital (?) – A facility to be classified as a general hospital shall provide inpatient care for medical or surgical patients, or both, and may include pediatric, obstetrical and newborn, psychiatric or rehabilitation patients. To be classified a specialized pediatric, psychiatric or rehabilitation hospital, a facility shall provide inpatient care in an exclusive specialty such as pediatrics, psychiatry or rehabilitation and shall have a medical staff and other professional or technical personnel especially qualified in the particular specialty for which the hospital is operated. (moved from 19 CSR 30-20.106 Inpatient Care Units)

(#) Hazardous Location – An area of a structure or building that poses a degree of hazard greater than that normal to the general occupancy of the building or structure.

(2219) Hospital-

(A) To be classified as a hospital, a facility shall provide inpatient care for medical or surgical patients, or both, and may include pediatric, obstetrical and newborn, psychiatric or rehabilitation patients. To be classified a specialized pediatric, psychiatric or rehabilitation hospital, a facility shall provide inpatient care in an exclusive specialty such as pediatrics, psychiatry or rehabilitation and shall have a medical staff and other professional or technical personnel especially qualified in the particular specialty for which the hospital is operated.

(B) The facility must be devoted primarily for the diagnosis, treatment, or care for not less than twenty-four (24) consecutive hours in any week of three (3) or more nonrelated individuals suffering from illness, disease, injury, deformity or other abnormal physical conditions, or devoted primarily to provide for not less than
twenty-four (24) consecutive hours in any week medical or nursing care for three (3)
or more nonrelated individuals and includes, (C) Building(s):
(1) Constructed to hospital standards as outlined in 19 CSR 30-20.030;
(2) Identified on the hospital’s license application as part of the facility;
(D) The term "hospital" does not include convalescent, nursing, shelter or boarding
homes as defined in chapter 198, RSMo.

Hospital emergency transfer policy—A document that represents
the usual and customary practices of a hospital with respect to the transfer of
patients. [The emergency department uses objective indicators of patient status in
relation to hospital capabilities to identify general classifications of patients who
should be considered for transfer to a hospital with the necessary capabilities,
and indicates the general classifications of patients the hospital has the
capabilities to receive through emergency transfer from another hospital. The
hospital emergency transfer policy does not supersede the authority of a
physician to determine whether patients should be transferred on a case-by-case
basis, but serves as an institutional baseline to assist physician staff in providing
consistent care decisions and is utilized for quality assurance review.]

Immediate and serious threat—Having caused, or is likely to
cause, serious injury, harm, impairment, or death to a patient.

Independent licensed practitioner—An individual who is a graduate of a
professional school and is licensed to practice as a health care provider in
Missouri.

Licensed practitioner—Any individual who is licensed and qualified to
practice a health care profession.

Infection control officer—An individual who is a licensed physician,
licensed registered nurse, has a bachelor’s degree in laboratory science or has
similar qualifications and has additional training or education preparation in
infection control, infectious diseases, epidemiology and principles of quality
improvement.

Infectious waste—Waste capable of producing an infectious disease.
For a waste to be infectious, it must contain pathogens with sufficient virulence
and quantity so that exposure to the waste by a susceptible host could result in an
infectious disease. Infectious waste shall include the following categories:
(A) Blood and blood products—All human blood and blood products including
serum, plasma and other components known or suspected to be contaminated with
a transmissible infectious agent;
(B) Contaminated surgical, dialysis and laboratory wastes—Wastes generated by surgery, dialysis and laboratory departments in the process of caring for hospital patients who have communicable diseases capable of being transmitted to others via those wastes;

(B) [(C)] Microbiologic cultures and stocks of infectious agents and associated biological [Cultures and stocks of infectious agents shall be designated as infectious waste because of the high concentrations of pathogenic organisms typically present in these materials. Included in this category are all cultures and stocks of infectious organisms as well as culture dishes and devices used to transfer, inoculate and mix cultures. Also included are animal carcasses, body parts and, bedding from animals contaminated with infectious agents];

(C) [(D)] Isolation wastes—Discarded waste[s] contaminated with excretions, exudates, and secretions from [generated by hospitalized] patients with highly [who have] communicable diseases treated in isolation [capable of being transmitted to others via those wastes];

(D) [(E)] Pathology wastes include [—Autopsy wastes which consist of] human tissues [organs,] and body parts [and body fluids] that are removed during surgery and autopsy [All these wastes shall be considered infectious waste]; and

(E) [(F)] Contaminated sharps—All discarded sharps including [hypodermic] needles, syringes [and] scalpels [blades] broken glass or other sharp items that have come in contact with potentially infectious material [defined as infectious are included.]

(F) Animal waste—Discarded material originating from animals inoculated with infectious agents during research, production of biological or pharmaceutical testing.

(285) [(20)] Inpatient—A person admitted into a hospital by a member of the medical staff for diagnosis, treatment or care.

(296) Intensive Care Unit—An appropriately equipped area of the hospital that provides patient care of a more intensive nature than the usual medical and surgical care, on the basis of physicians' orders and approved nursing care plans. These units are staffed with specially trained nursing personnel and contain monitoring and specialized support equipment for patients who, because of shock, trauma or other life-threatening conditions or surgeries, require intensified comprehensive observation and care.

(#) Isolation — See Seclusion

(27) Intermediate care unit. Any unit other than a residential care unit or skilled nursing unit which is utilized by a hospital to provide twenty-four (24)-hour accommodation, board, personal care and basic health and nursing care services under daily supervision of a licensed nurse.
Laboratory technologists — an individual who has graduated from a medical technology program approved by a nationally recognized body or has the documented equivalent education, training and experience.

Licensed practitioner: Any individual who is licensed in Missouri or in another state and is qualified to practice a health care profession.

Long-term care unit. A unit attached to or contained within a hospital that is operated solely or in combination as a skilled nursing unit, or an intermediate care unit for a residential care unit.

Medical services — Those preventive, diagnostic and therapeutic measures performed by, or at the request of, members of the medical staff or a independent licensed practitioner in outpatient services.

Neonatal Continuing or Intermediate Care Nursing Unit — A unit that provides intermediate and/or recovery care and some specialized services, including immediate resuscitation, intravenous therapy, and capacity for prolonged oxygen therapy and monitoring.

Neonatal intensive care — A unit that must be separate from the newborn nursery providing intensive care to all sick infants, including those with the very lowest birth weights (less than 1500 grams). NICU has potential for providing mechanical ventilation, neonatal surgery and special care for the sickest infants born in the hospital or transferred from another institution.

Newborn infants (as used under pediatric services) — An infant who was born within the last seventy-two hours and has not been previously discharged and readmitted.

Never event— an event, condition or occurrence included as a serious reportable event as listed in Table A of the July 31, 2008, memorandum issued by the Center for Medicare and Medicaid Services (CMS), which is incorporated herein and available at https://downloads.cms.gov/cmsgov/archiveddownloads/SMDL/downloads.smd073108.pdf.

Observation – the act of paying close attention to someone or something in order to obtain information.
Occupational therapist—An individual who is currently licensed under chapter 324, RSMo, by the Board of Occupational Therapy to practice occupational therapy in the State of Missouri. [graduate of an occupational therapy program approved by a nationally recognized accrediting body, or who currently holds certification by the American Occupational Therapy Association as an occupational therapist or who has the documented equivalent in training or experience and is currently competent in the field.]

Operator—[Shall mean any person as defined by section 197.020, RSMo who is licensed or required to be licensed under the provisions of sections 197.020–197.120, RSMo to establish, conduct or maintain a hospital. The term person shall mean any person determined by the department to have the following:] A person with
(A) Ultimate responsibility for making and implementing decisions regarding the operation of the hospital; and
(B) Ultimate financial control of the operation of the hospital, including any management consultant or contracted entity who exercises control over the operation of the facility on a day to day basis.

Outpatient – A person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services (rather than supplies alone) from the hospital or CAH.

PALS—The American Heart Association’s pediatric advanced life support program. PALS may be used interchangeably with APLS where required.

Patient – A person who presents to the hospital seeking diagnosis, treatment, or care.

Pharmacist—An individual who is a graduate of a school or college of pharmacy and is currently licensed under chapter 338, RSMo, to practice pharmacy in the State of Missouri.

Pharmacist Intern – an individual who is currently licensed under chapter 338, RSMo, as a pharmacist intern in the State of Missouri.

Pharmacy technician—an individual who is currently registered under chapter 338, RSMo, as a pharmacy technician in the State of Missouri.

Physical therapist—An individual who is currently licensed under chapter 334, RSMo, to practice professional physical therapy in the State of Missouri.
(47) [(25)] Physician—An individual who [has received a Doctor of Medicine or Doctor of Osteopathy degree and] is currently licensed under chapter 334, RSMo, to practice medicine in Missouri.

(48) [(26)] Podiatrist—An individual who [has received a Doctor of Podiatric Medicine degree and] is currently licensed under chapter 330, RSMo, to practice podiatry in Missouri.

(49) Premise—As specified in the hospital license application, the buildings, floors, or areas that are to be included in the license pursuant to 197.052 RSMo.

(50) [(27)] Psychologist—An individual who is currently licensed under chapter 337, RSMo, to practice psychology [by the State Committee of Psychologists] in Missouri [under the provisions of Chapter 337, RSMo].

[(41) [(30)] Qualified medical record technician—An accredited record technician who has successfully passed the appropriate accreditation examination conducted by the American Medical Record Association or who has the documented equivalent in education and training.]

(51) [(33)] [Qualified] Radiologic technologist—An individual who is a graduate of a program in radiologic technology approved by [if] The [Council on Medical Education of the American Medical Association] Joint Review Committee on Education in Radiologic Technology or who has the documented equivalent [in] education, [and] training, and experience.
(52) [(35)] Registered professional nurse—An individual who is [a graduate of an approved school of nursing and who is] licensed under chapter 335, RSMo, to practice as a registered professional nurse in the State of Missouri.

(53) [(36)] Registered or certified Respiratory Care Practitioner [therapist]—An individual who is [has been] licensed under chapter 334, RSMo, to practice respiratory care in the State of Missouri. [registered or certified by the National Board for Respiratory Therapy, Inc. after successfully completing all education, experience and examination requirements or an individual who has been registered or certified prior to November 11, 1982, by an organization acceptable to the Department of Health and Senior Services.]

(54) Resident—A person who by reason of aging, illness, disease or physical or mental infirmity requires care and services furnished by a long-term care unit and who resides in this a unit and is cared for, treated or accommodated there for a period exceeding twenty-four (24) consecutive hours within the unit for care and treatment.

(#) Restraints – Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely.

(55) [(37)] Root cause analysis—A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.

(56) [(38)] Sentinel event—An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

(#) Seclusion - is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(57) Skilled nursing unit. Any unit other than a residential care unit or an intermediate care unit which is utilized by a hospital to provide for twenty-four (24)-hour accommodation board and skilled nursing care and treatment services. Skilled nursing care and treatment services are those services commonly performed by or under the supervision of a registered nurse for individuals requiring twenty-four (24)-hour-a-day care by licensed nursing personnel.

Seriously Mentally Ill
Social worker—An individual who is licensed under chapter 337, RSMo, to practice social work in the State of Missouri. [clinical social worker or a person who has a bachelor’s degree in social work or a master’s degree in social work].

Specialized inpatient care services [unit]—An appropriately equipped area of the hospital where there is a concentration of physicians, nurses and others who have special skills and experience to provide optimal medical care for critically-ill patients and may include, but not be limited to intensive care, burn, coronary, neonatal and oncology units services.

Telemedicine or telehealth — The provision of clinical services to patients by physicians and practitioners from a distance via electronic communications.

Transfer agreement—A document which sets forth the rights and responsibilities of two (2) hospitals regarding the inter-hospital transfer of patients.

Unit—A functional division or facility of the hospital.

Unlicensed Assistive Personnel (UAP)—unlicensed health care personnel who provide direct patient care twenty-five percent (25%) or more of the time, under the delegation and supervision of a registered professional nurse. Individuals who provide a specific job function such as, but not limited to, phlebotomist, radiology technician or patient transporter are not included in this definition.


PROPOSED AMENDMENT

19 CSR 30-20.015 Administration of the Hospital Licensing Program. The department is adding new sections (1) and (4); renumbering thereafter; amending the Purpose statement, sections (1) through (16); and deleting the form that follows the rule.

PURPOSE: This rule formalizes the hospital licensing policies being carried out by the Department of Health. It prescribes procedures for the review of hospital records, acceptance of plans of deficiency correction and suspension of describes the license application, survey and reporting process for a hospital and process for disciplining a hospital license.

(1) State Licensure Requirements.

(A) This rule incorporates by reference 42 CFR 485, Medicare Conditions of Participation: Critical Access Hospitals; published May 16, 2012; effective July 16, 2012, for Missouri licensed critical access hospitals. Missouri licensed critical access hospitals shall strictly meet the Medicare Conditions of Participation and surveys performed for state licensure will be conducted per Medicare standards.

(B) This rule incorporates by reference 42 CFR 482, Medicare Conditions of Participation: Hospitals; published May 16, 2012; effective July 16, 2012, for Missouri licensed hospitals. Missouri licensed hospitals shall strictly meet the Medicare Conditions of Participation and surveys performed for state licensure will be conducted per Medicare standards.

(C) This rule incorporates by reference 42 CFR 482, Medicare Conditions of Participation: Psychiatric Hospitals; published June 17, 1986; effective August 4, 1986, for Missouri licensed psychiatric hospitals. Missouri licensed psychiatric hospitals shall strictly meet the Medicare Conditions of Participation and surveys performed for state licensure will be conducted per Medicare standards.

[(1)] (2) Persons intending to operate a hospital shall submit information to the Department of Health and Senior Services, as set out in the application form (MO 580-0007(8-017)) which is incorporated by reference in this rule as published by the department on (date) and available on the department’s website at health.mo.gov or by contacting the department at P.O. Box 570, Jefferson City, MO 65102-0570 [included herein]. This rule does not incorporate any subsequent amendments or additions. Within thirty (30) days after receipt of the application, the applicant will be notified of any omitted information or documents. After sixty (60) days any incomplete application is null. DHSS may deny a license application in any case which it finds that there has been a substantial failure to comply with the requirements for hospitals in Chapter 197, RSMo, and the regulations promulgated thereunder. Each application for license to operate a hospital shall be accompanied by the appropriate licensing fee, except applications from governmental units, required by section 197.050, RSMo. Each license shall be issued for the premises and persons named in the application.
(2) Each license shall be issued only for the premises identified on the application for hospital license and entity named in the application. All locations included in the hospital application for hospital license shall meet the definition of "premises" as stated in 19 CSR 30-20.011. No license shall be issued unless the applicant is in substantial compliance with Chapter 197, RSMo and the regulations promulgated thereunder. A license, unless sooner revoked, shall be issued for a period of up to a year. If during the period in which a license is in effect, a licensed operator which is a partnership, limited partnership, or corporation undergoes any of the following changes, whether by one (1) or by more than one (1) action, the operator shall within fifteen (15) working days of such change apply for a new license:

(A) With respect to a partnership, a change in the majority interest of general partners;
(B) With respect to a limited partnership, a change in the general partner or in the majority interest of limited partners;
(C) With respect to a corporation, a change in the persons who own, hold or have the power to vote the majority of any class of securities issued by the corporation. If the corporation does not have stock, a change of owner occurs when the emerging entity has a new federal tax number; or
(D) The board of directors with management control is an entity other than the licensed operator.

(4) The operator of a licensed hospital shall notify DHSS in writing within fifteen (15) days of:

(A) A change of ownership of the hospital;
(B) Any extensive modification, modification or reconstruction, as identified in NFPA 101, 2012 edition- Chapter 43, of the licensed premises;
(B) Anytime more than ten percent (10%) of the number of total licensed beds are not immediately available (within twenty-four (24) hours) for use as designated, for a period exceeding ten (10) days.

(5) An operator of two (2) or more licensed hospitals may submit application to the Department of Health and Senior Services to operate the hospitals as a single licensed hospital. The two (2) or more licensed hospitals may be separated by a distance which can be traveled in no more than one (1) hour by customary ground transportation in normal weather conditions. The operator shall designate a permanent hospital base from which the one (1) -hour travel distance is determined. If the application is approved, the hospitals may be named on the licensure application and a single license issued. [Also, an operator of a licensed hospital may submit a proposal to provide, at a minimum, all of the required patient care services at a geographical location which at the time of the proposal is not a part of the licensed hospital. The location shall be within a one (1) -hour travel distance by customary ground transportation in normal weather conditions.] Before the Department of Health and Senior Services approves the application, the applicant shall submit an operational proposal to the director of the Department of Health and Senior Services for approval. At a minimum the proposal shall include:

(A) A description of the patient care services that will be provided at each geographical location and how they will be integrated with patient care services at other geographical locations which will be operated under the single license. [The description shall include
justification to support the applicant’s allegation that the combined patient care hospital services will exceed the current benefits that are derived by the community(ies) where each individual currently licensed hospital is located. Or, if the operator currently is not providing the service within the geographical location contained in the proposal, there shall be evidence the service is needed in that location;

(B) A description of the organizational structure of the proposed single licensed hospital;
(C) Documentation of evidence that the hospital’s facilities in each geographical location named in the proposal will be owned or leased by the same operator and that the services are operated under common management;
(D) Assurance that the hospital’s operation in each geographical location will be held out to the public under a common name;
(E) Assurance the hospital’s services in each geographical location will be subject to the bylaws and operating decisions of the same governing body;
(F) Assurance that members of the medical staff in each geographical location will be under the direction of one (1) physician leader [directed by a common medical director] and will be subject to the same medical staff bylaws and operating decisions of a common medical staff;
(G) Assurance the hospital’s operations in each geographical location will be administered by a common chief executive officer through appropriate delegation of duties;
(H) Assurance the licensed hospital’s services in each geographical location will be integrated and, when services are provided at multiple locations, that they will be supervised by a common director who is provided with adequate assistance in supervision of the services;
(I) Assurance that the single licensed hospital’s medical records department is integrated and the records are easily accessible to patient care staff;
(J) Assurance the applicant’s proposal is not in violation of other federal, state and local regulations;
(K) Assurance that the applicant, either separately at each geographical location or in combination, will provide all required patient care services in accordance with acceptable standards of practice. Emergency[, including emergency] services, in accordance with Chapter 197, RSMo and 19 CSR 30-20.021(3) [and in accordance with acceptable standards of practice:] shall be provided at each location.
(L) [Assurance that services and beds at one (1) geographical location will not be reallocated to another geographical location prior to the operator requesting and obtaining approval from the Certificate of Need program, whenever appropriate, and the Department of Health;]
[(M)] Approval from the Certificate of Need program if a Certificate of Need is required under [the operator’s proposal includes a request to provide a patient care service in a geographical location of the hospital which is not currently a part of the hospital’s license when the proposal is subject to the Missouri Certificate of Need law,] sections 197.300–197.365, RSMo;
[(N)] (M) Assurance that skilled nursing unit[, intermediate care unit and residential care unit] services provided within the licensed hospital are physically located at a geographical location of the hospital where all of the required patient care services are
provided on-site in accordance with Chapter 197, RSMo and [19 CSR 30-20.021(3)] 19
CSR 30-20.050:

[(O)] (N) Assurance that the applicant’s proposal will not jeopardize the health and safety
of individuals who reside within the geographical locations which will be served by the
single licensed hospital. The applicant shall demonstrate that the proposal contains
provision for services which exceed or are comparable to the services currently being
provided to the community, or will provide adequate justification to convince the
Department of Health and Senior Services the service is no longer needed within the
geographical location where the service is currently provided; and

[(P)] (O) Assurance that the applicant presented the proposal at a public hearing within
the community where the currently licensed hospital(s) is located. The proposal shall
provide evidence that the entire community was adequately notified at least two (2)
weeks in advance, of the public hearings. The written record of the hearings, including
the community response to the proposal, shall be submitted to the Department of Health
and Senior Services as a part of the applicant’s proposal. The Department of Health and
Senior Services shall be given two (2) weeks advance notice of the public hearings. The
Department of Health and Senior Services may consider the information presented as part
of the determination process.

[(4)] (6) The license shall state the maximum licensed bed capacity, [the person(s) to whom
granted and] the hospital name, issue date, [and] expiration date and additional information,
such as a specialty hospital designation, that the department may require. At least forty-five (45)
days prior to the expiration date of an existing license, the department shall notify the operator
that the license application is due for renewal. [A re-licensure] An annual application shall be
submitted no more than ninety (90) days and not less than thirty (30) days prior to the expiration
date of the existing license. Each application for license, except application from governmental
units, shall be accompanied by a licensing fee in accordance with section [197.210] 197.050,
RSMo.

[(5)] (7) Appointed representatives of the Department of Health and Senior Services shall be
allowed to inspect a hospital as required in section 197.100, RSMo. The chief executive officer
or designee shall grant access to information requested by the department for the purpose of
evaluating compliance with hospital licensing requirements. Requested records may include, but
are not limited to, incident reports, quality of care reports, peer review reports, committee
minutes, policies and procedures, training records, medical records or any other documents
which are necessary to complete the inspection. All information and reports obtained by the
Department of Health and Senior Services shall be kept confidential as required in section
197.477, RSMo.

[(6)] (8) Appointed representatives of the Department of Health and Senior Services, Bureau of
Hospital [Licensing and Certification] Standards shall be allowed to review patient medical
records and hospital employee personnel records in the course of conducting an investigation of
allegations against an employee or previous employees of a hospital or allegations of
substandard care regarding a patient transferred to the hospital from another licensed facility.
The representatives shall first provide written assurance that information obtained from the
patient’s medical record or from the employee’s personnel record will be maintained
confidential].
The operator shall have a written policy pertaining to employees reporting mismanagement of violations of applicable laws and rules. At a minimum the policy shall include the following provisions:

(A) No supervisor or individual with hiring or firing authority in a licensed hospital shall prohibit any of its employees from discussing the operations of the hospital, either specifically or generally, with any representatives of the department; and

(B) No supervisor or individual with authority to hire and fire in a licensed hospital shall prohibit his/her employees from disclosing information which the employee reasonably believes evidences a violation of any applicable state or federal law or regulation. This subsection shall not be construed as—
1. Permitting an employee to leave his/her assigned work areas during normal work hours without following applicable rules and policies pertaining to leaves, unless the employee is requested by the Department of Health and Senior Services to officially appear before department representatives;
2. Authorizing an employee to represent the employee’s personal opinions as the opinions of his/her employer; or
3. Precluding the operator from taking appropriate disciplinary actions against any employee.

Inspection Survey Process.

(A) The department shall conduct licensure compliance inspections surveys of hospitals as required by section 197.100, RSMo. Initial surveys shall be announced to the facility at least seventy-two (72) hours in advance. Complaint investigations may be unannounced.

(B) Interviews with staff, patients, and visitors shall be conducted in private, unless otherwise requested by the person being interviewed. Staff serving as a witness to an interview or an observation shall only observe and not participate.

Inspection Survey Findings.

(A) Whenever an authorized representative of the department finds, during an inspection a survey, that a hospital is not in compliance with the provisions of the Hospital Licensing Law, [sections 197.010–197.120] Chapter 197, RSMo, and regulations promulgated thereunder, the chief executive officer or designee shall be informed of the general nature of findings in an exit conference conducted prior to the representative’s departure from the premises. Within ten (10) working days after each licensing inspection survey, a written report shall be prepared by the department detailing the specifics of each deficiency. A copy of the report and a written correction order shall be sent to the hospital’s chief executive officer or designee. The report shall state each deficiency separately and shall reference the specific statute or administrative rule violated. If the facility believes that deficiencies are not applicable or are not based upon laws or rules, a request for review may be submitted to the office of the director or designee of the department.

(B) Should the findings of the inspection survey constitute an immediate jeopardy and serious threat to the safety or health of the patients, public or hospital staff, a
condition of substantial noncompliance shall be considered to exist. The department representative shall verbally convey any determination of substantial noncompliance to the chief executive officer or designee at the exit conference. Findings of substantial noncompliance shall be documented in the normal reporting method described in subsection [(9)(A)] [(10)(A)] of this rule.

(C) The following guidelines, applicable to the [inspection] survey, shall be used by the licensing representative to determine if a finding during [an inspection] a survey constitutes an immediate and serious threat to the health and safety of one (1) or more patients. The guidelines used to determine immediate and serious threat serve only as guides for authorized department representatives to use when making the determination. **An immediate and serious threat includes but shall not be limited to:**

1. Failure to protect from abuse—
   A. Serious injuries such as head trauma or fractures;
   B. Non-consensual sexual interactions; e.g., sexual harassment, sexual coercion or sexual assault;
   C. Unexplained serious injuries that have not been investigated;
   D. Staff striking or roughly handling an individual;
   E. Staff yelling, swearing, gesturing or calling an individual derogatory names;
   F. Bruises around the breast or genital area; or
   G. Suspicious injuries; e.g., black eyes, rope marks, cigarette burns, unexplained bruising.

2. Failure to prevent neglect—
   A. Lack of timely assessment of individuals after injury;
   B. Lack of supervision for individual with known special needs;
   C. Failure to carry out doctor’s orders;
   D. Repeated occurrences such as falls which place the individual at risk of harm without intervention;
   E. Access to chemical and physical hazards by individuals who are at risk;
   F. Access to hot water of sufficient temperature to cause tissue injury;
   G. Non-functioning call system without compensatory measures;
   H. Unsupervised smoking by an individual with a known safety risk;
   I. Lack of supervision of cognitively impaired individuals with known elopement risk;
   J. Failure to adequately monitor individuals with known severe self-injurious behavior;
   K. Failure to adequately monitor and intervene for serious medical/surgical conditions;
   L. Use of chemical/physical restraints without adequate monitoring;
   M. Lack of security to prevent abduction of infants;
   N. Improper feeding/positioning of individual with known aspiration risk;
   O. Inadequate supervision to prevent physical altercations; or
   P. Lack of appropriate use, care planning or monitoring of patients when any type of [restraint] restraint, including but not limited to physical or chemical restraint, is utilized.

3. Failure to protect from psychological harm—
A. Application of chemical/physical restraints without clinical indications;
B. Presence of behaviors by staff such as threatening or demeaning,
    resulting in displays of fear, unwillingness to communicate, and recent
    or sudden changes in behavior by individuals; or
C. Lack of intervention to prevent individuals from creating an
    environment of fear.

4. Failure to protect from undue adverse medication consequences and/or failure
to provide medications as prescribed—
A. Administration of medication to an individual with a known history of
    allergic reaction to that medication;
B. Lack of monitoring and identification of potential serious drug
    interaction, side effects, and adverse reactions;
C. Administration of contraindicated medications;
D. Pattern of repeated medication errors without intervention;
E. Lack of diabetic monitoring resulting or likely to result in serious
    hypoglycemic or hyperglycemic reaction; or
F. Lack of timely and appropriate monitoring required for drug titration.

5. Failure to provide adequate nutrition and hydration to support and maintain
    health—
A. Food supply inadequate to meet the nutritional needs of the individual;
B. Failure to provide adequate nutrition and hydration resulting in
    malnutrition; e.g., severe weight loss, abnormal laboratory values;
C. Withholding nutrition and hydration without advance directive; or
D. Lack of potable water supply.

6. Failure to protect from widespread nosocomial infections; e.g. failure to
    practice standard precautions, failure to maintain sterile techniques during
    invasive procedures and/or failure to identify and treat nosocomial infections—
A. Pervasive improper handling of body fluids or substances from an
    individual with an infectious disease;
B. High number of infections or contagious diseases without appropriate
    reporting, intervention and care;
C. Pattern of ineffective infection control precautions; or
D. High number of nosocomial infections caused by cross contamination
    from staff and/or equipment/supplies.

7. Failure to correctly identify individuals—
A. Blood products given to wrong individual;
B. Surgical procedure/treatment performed on wrong individual or wrong
    body part;
C. Administration of medication or treatments to wrong individual; or
D. Discharge of an infant to the wrong individual.

8. Failure to safely administer blood products and safely monitor organ
    transplantation—
A. Wrong blood type transfused;
B. Improper storage of blood products;
C. High number of serious blood reactions;
D. Incorrect cross match and utilization of blood products or transplantation organs; or
E. Lack of monitoring for reactions during transfusions.

9. Failure to provide safety from fire, smoke and environment hazards and/or failure to educate staff in handling emergency situations—
   A. Nonfunctioning or lack of emergency equipment and/or power source;
   B. Smoking in high risk areas;
   C. Incidents such as electrical shock, fires;
   D. Ungrounded/unsafe electrical equipment;
   E. Widespread lack of knowledge of emergency procedures by staff;
   F. Widespread infestation by insects/rodents;
   G. Lack of functioning ventilation, heating or cooling system placing individuals at risk;
   H. Use of non-approved space heaters, such as kerosene, electrical, in resident or patient areas;
   I. Improper handling/disposal of hazardous materials, chemicals and waste;
   J. Locking exit doors in a manner that does not comply with NFPA 101;
   K. Obstructed hallways and exits preventing egress;
   L. Lack of maintenance of fire or life safety systems; or
   M. Unsafe dietary practices resulting in high potential for food-borne illnesses.

10. Failure to provide initial medical screening, stabilization of emergency medical conditions and safe transfer for individuals and women in active labor seeking emergency treatment—
    A. Individuals turned away from emergency room (ER) without medical screening exam;
    B. Women with contractions not medically screened for status of labor;
    C. Absence of ER or obstetrical (OB) medical screening records;
    D. Failure to stabilize emergency medical condition; or
    E. Failure to appropriately transfer an individual with an unstabilized emergency medical condition.

(A) Ten (10) [working] calendar days following receipt of the written [inspection] survey report, the chief executive officer or designee shall provide the department with a written plan for correcting the cited deficiencies or a request for reconsideration of the deficiency. The plan of correction shall specify the means the hospital will employ for correcting the cited deficiencies and the date that each corrective measure will be completed. If a request for reconsideration is submitted, the request shall contain rationale or documentation to provide evidence that the deficiency should not have been cited. Failure of the facility to submit a plan of correction or a request for reconsideration of the deficiency acceptable to the director of the department or designee—within the time frame specified—shall be grounds for the department to [suspend] take disciplinary action against the facility’s license if there remains a substantial failure to comply with the requirements for hospitals established under [sections 197.010–197.120] Chapter
197, RSMo and [19 CSR 30-20.011–19 CSR 30-20.070] regulations promulgated thereunder. The operator has the right to appeal the department’s decision in accordance with section 197.071, RSMo.

(B) Upon receipt of the required plan of correction for achieving licensure compliance, the department shall review the plan to determine the appropriateness of the corrective action. If the plan is acceptable, the department shall notify the chief executive officer or designee, in writing, and indicate that implementation of the plan should proceed. If the plan is not acceptable, the department shall notify the chief executive officer or designee, in writing, and indicate the reasons why the plan is not acceptable. Within ten (10) working days from the receipt of the notice, a revised, acceptable plan of correction shall be provided to the department.

(11) Follow-up [Inspection] Surveys. Upon expiration of the target dates for correction of deficiencies specified in the approved plan of correction, the department may make a follow-up [inspection] survey to determine whether the required corrective measures have been acceptably accomplished. If the follow-up [inspection] survey finds the facility fails to comply with the [provisions of the Hospital Licensing Law, sections 197.010–197.120, RSMo and 19 CSR 30-20.011–19 CSR 30-20.070] the requirements for hospitals in Chapter 197, RSMo, and regulations promulgated thereunder, the department may take disciplinary action [to suspend or to revoke] against the operator’s license to operate the hospital or to provide specific services. The operator has the right to appeal the department’s decision in accordance with section 197.071, RSMo.

(12) If, for a period in excess of fourteen (14) days, a facility ceases to provide patient care or to otherwise operate as a hospital within the definition of section 197.020.2, RSMo, except in the case of a strike, an act of God, manmade disaster or written approval of the department, the facility shall surrender its license to the department. The facility shall not operate again as a hospital until an application for a hospital license is submitted with assurance that the facility complies with the requirements [in 19 CSR 30-20.030] for hospitals in Chapter 197, RSMo, and regulations promulgated thereunder and the Department of Health and Senior Services issues a license.

(13) Requested Suspension of License.
If any hospital wishes to cease operation for a period of time but retain its current hospital license, the Department of Health and Senior Services, upon written request from the licensed operator, may grant approval for suspension of the hospital’s license for a specified time.

(A) Not less than fourteen (14) days prior to cessation of patient services at the hospital, the licensed operator shall submit to the department a written request for continuance.
(B) The written request for the suspension of the license shall include the reasons for cessation of patient services, the anticipated length of cessation of patient services, what safeguards the hospital will institute to provide security to the institution, the preventive maintenance measures used to assure that all equipment will be kept in good working order and evidence that the hospital is financially solvent to meet the conditions of the request and will remain so throughout the period of cessation of patient services.
(C) Approval may be granted only for the suspension of a hospital’s current license if the cessation of patient services is for one (1) of the following reasons:
1. The renovation of the hospital’s facility to upgrade to current licensure standards and to correct licensure or federal certification physical plant deficiencies;
2. The transfer of the operation of the hospital to a new operator to allow sufficient time for the new operator to obtain a new license; or
3. Other reasons which will not result in a deterioration of the hospital physical plant or its programs and which will be in the best interest of the citizens it serves.

D) The suspension of a hospital’s current license shall not exceed ninety (90) days beyond the date of cessation of patient services for ownership transfer. The suspension of a hospital’s current license shall not exceed one hundred eighty (180) days beyond the date of cessation of patient services for renovation construction. The department may not grant more than one (1) suspension to a hospital’s licensed operator within any twelve (12)-month period and shall grant no suspension for a period of more than one hundred eighty (180) days from the date of cessation of inpatient services.

E) No inpatients shall be housed within the hospital from the initial date of cessation of inpatient services until operation of the hospital is restored with Department of Health approval.

F) No inpatient services shall be provided in the hospital during the period of time that inpatient services are discontinued.

G) When suspension of the license is requested for a renovation or construction proposal, the licensed operator shall submit plans for the renovation to the department for review and shall have received the department’s approval of those plans prior to the date of cessation of patient services at the hospital.

H) The licensed operator shall notify the department no less than fourteen (14) days prior to the resumption of inpatient services that the hospital is ready for review/inspection for approval to reoccupy the hospital with inpatients.

I) Within ten (10) working days of notification, the department shall respond in writing to the licensed operator with the findings of its review/inspection for the resumption of licensed hospital services at the hospital.

[(14)] (16) Involuntary Suspension or Revocation of the License.

A) Whenever the department determines that substantial noncompliance exists in a hospital, the department may take [immediately suspend or revoke] immediate disciplinary action against the license of the facility or order cessation of use of any portion of the noncompliant services or buildings.

B) The department shall document its action in writing in addition to the report detailing the findings of the inspection. A copy shall be submitted to the hospital’s chief executive officer or designee.

C) The hospital shall expedite corrections required to relieve the involuntary suspension or revocation.

D) The operator may elect to seek appeal or relief from the Administrative Hearing Commission in accordance with section 197.071, RSMo, or the operator may elect to first request a review of the action by the office of the director of the department.
In accordance with the requirements of the Missouri Hospital Licensing Law (sections 197.010 through 197.120, RSMo), application is hereby made for a license to conduct and maintain a hospital (see “Definitions,” section 197.020, subsection 2., RSMo).

<table>
<thead>
<tr>
<th>NAME OF HOSPITAL (NAME TO APPEAR ON LICENSE)</th>
<th>TELEPHONE NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDRESS (STREET AND NUMBER)</td>
<td>CITY</td>
</tr>
<tr>
<td>CHIEF EXECUTIVE OFFICER (FULL NAME)</td>
<td>TITLE</td>
</tr>
<tr>
<td>NEXT IN CHARGE (FULL NAME)</td>
<td>TITLE</td>
</tr>
<tr>
<td>TYPE OF FACILITY</td>
<td>GENERAL HOSPITAL</td>
</tr>
<tr>
<td>OWNERHIP AND MANAGEMENT (CHECK ONLY ONE)</td>
<td></td>
</tr>
<tr>
<td>A. GOVERNMENTAL</td>
<td></td>
</tr>
<tr>
<td>□ DISTRICT</td>
<td>□ COUNTY</td>
</tr>
<tr>
<td>B. NON-GOVERNMENTAL</td>
<td>NON-PROFIT</td>
</tr>
<tr>
<td>NAME OF GOVERNING BODY</td>
<td></td>
</tr>
<tr>
<td>CHIEF OFFICER OF GOVERNING BODY (FULL NAME)</td>
<td>TITLE</td>
</tr>
<tr>
<td>LEGAL NAME OF OPERATING CORPORATION</td>
<td></td>
</tr>
<tr>
<td>IF OPERATED BY MANAGEMENT CONSULTANT, NAME OF FIRM</td>
<td></td>
</tr>
<tr>
<td>FISCAL YEAR</td>
<td>MO</td>
</tr>
<tr>
<td>COMPLETED AND RETURNED MOST RECENT ANNUAL SURVEY OF MISSOURI HOSPITALS? (FOR RENEWAL APPL ONLY)</td>
<td>YES</td>
</tr>
<tr>
<td>PROFESSIONAL DATA</td>
<td></td>
</tr>
<tr>
<td>ACTIVE STAFF</td>
<td>NUMBER</td>
</tr>
</tbody>
</table>
| RADIOLIGIST (NAME) | ARCHITECT (NAME) | PATHOLOGIST (NAME) | }
| DR. OF NURSING SERVICE (NAME) | DR. MEDICAL RECORDS (NAME) | DR. PHYSICAL PLANT (NAME) |
| DR. DIETARY SERVICE (NAME) | DR. PHYSICAL PLANT (NAME) |
| ACCREDITED? | YES | NO | ACCREDITED BY | YES | NO |
| □ YES | □ NO | | □ JCIAH | □ AOA | |
| SCHOOL OF NURSING | YES | NO | APPROVED FOR RESIDENT INTERNSHIP | YES | NO |
| □ YES | □ NO | NUMBER OF RESIDENTS | NUMBER OF INTERNS |
BED DESIGNATION BY SERVICES (INDICATE TOTAL NUMBER OF BEDS IN EACH CATEGORY)

<table>
<thead>
<tr>
<th>MEDICAL/SURGICAL</th>
<th>ALCOHOL/DRUG ABUSE</th>
<th>LTC TOTAL</th>
<th>NEONATAL ICU</th>
<th>OTHER (SPECIFY SERVICE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBSTETRICAL</td>
<td>PSYCHIATRIC</td>
<td>SKILLED NURSING</td>
<td>INTERMEDIATE CARE</td>
<td>NURSERY BASSINETS</td>
</tr>
<tr>
<td>PEDIATRIC</td>
<td>ICU-CCU</td>
<td>REHABILITATION</td>
<td></td>
<td>TOTAL BEDS NUMBER</td>
</tr>
</tbody>
</table>

NOTE: ANY CHANGES IN TOTAL BED COMPLEMENT SINCE LAST APPLICATION (INCREASE OR DECREASE) MUST BE FULLY EXPLAINED.

CERTIFICATION

STATE OF MISSOURI

City of ____________________________  }   SS.
County of __________________________

being duly sworn or affirmed by ____________________________
and ____________________________

being duly sworn by me on ___________ oaths, deposes and says that ____________________________ have read the foregoing application and that the statements contained therein are correct and true and of ____________________________ knowledge; and further gives assurance of the ability and intention of the ____________________________ to comply with the regulations and codes promulgated under the Missouri Hospital Licensing Law (sections 197.010 through 197.120, RSMo).

It is further certified that the ____________________________ will comply with all recommendations for correction and/or improvements as contained in the most recent Licensing Survey Report prepared by the Department of Health and Senior Services and submitted to said Hospital.

Signed ____________________________
CHIEF EXECUTIVE OFFICER

Signed ____________________________
HOSPITAL CHIEF EXECUTIVE OFFICER

NOTARY PUBLIC EMBOSSED OR BLACK IN PIGMENT STAMP SEAL

STATE

COUNTRY (OR CITY OF ST. LOUIS)

SUBSCRIBED AND SWORN BEFORE ME, THIS DAY OF ____________, ____________ YEAR

NOTARY PUBLIC SIGNATURE

MY COMMISSION EXPIRES ____________, ____________

NOTARY PUBLIC NAME (TYPED OR PRINTED)

USE RUBBER STAMP IN CLEAR AREA BELOW.
In accordance with the requirements of the Missouri Hospital Licensing Law, application is hereby made for a license to conduct and maintain a hospital.

<table>
<thead>
<tr>
<th>License No.</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Certificate No.</th>
<th>Date Mailed</th>
</tr>
</thead>
</table>

**Name of Hospital (Name to appear on license):**

**Telephone No.:**

**Legal Name of Hospital:**

**Street Address:**

**City and Zip Code:**

**County:**

**Chief Executive Officer (Full Name):**

**Title:**

**Email:**

**Next in Charge (Full Name):**

**Title:**

**Email:**

The hospital fiscal year starts on (MONTH/DAY)__________ and ends on (MONTH/DAY)__________

**Ownership and Management (Check only one):**

**A. Governmental:**

- District
- City-County
- County
- Other (Specify)

**B. Non-Governmental:**

**Non Profit:**

- Church Operated
- Church Affiliated
- Other Non-Profit
- Other (Specify)

**Proprietary:**

- Individual
- Partnership
- Corporation
- Other (Specify)

**Legal Name of Operating Corporation:**

**If operated by management consultant, name of firm:**

**C. Attach an organizational chart which details all executive boards and/or supervisory boards for any entity that maintains management authority over the hospital or an ownership interest in this hospital of more than 50% to include the directors of each required service.**

**The hospital has completed and returned the most recent annual survey of Missouri hospitals:**

**Yes**

**No**

**Accreditation:**

**Accredited:**

- Yes
- No

**Accredited by:**

**Deemed:**

- Yes
- No

**Bed Designation by Services:** (Indicate total beds in each category). If any of the beds have been converted to non-patient use or no longer meet the definition of a patient care room type as defined under 19 CSR 30-20.030 for construction standards please do not include those beds on the list.

- Medical-Surgical
- Psychiatric
- Obstetrical
- Neonatal ICU
- Nursery Bassinets
- Rehabilitation
- ICU-CCU
- Pediatric
- Long Term Care
- Alcohol/Drug Abuse
- Other (Specify Service)

**Total Beds**

**Change from Previous Total?**

**ER Bays/Beds or Suites**

**Swing Beds**

*(Not included in bed count)*

**Note:** Attach an explanation for any changes in total bed complement since last application.

MO580-0007 (08-17)

HL-11
## OTHER

### Construction/Renovation

1. New hospitals - attach Certificate of Need approvals if applicable
2. Renovations or construction projects during this licensure period should be submitted in accordance with 19 CSR 30-20.030.
3. Provide a copy of all DHSS current, approved variances.
   a. If new variance(s) is requested, please submit in accordance with 19 CSR 30-20.142

### Premises

For all locations that will be identified as premises, as defined by 19 CSR 30-20.011(49) please provide a map or drawing of the premises to illustrate the location of each building.Attach a listing of all buildings with each listed by name, address and type of patient service offered.

### Co-location status

Is there another provider or licensed entity, or a satellite location of another provider or licensed entity, that occupies space in a building used by the hospital, or in one or more entire buildings located on the same campus as buildings used by the hospital?

- [ ] Yes ____________
- [ ] No ____________

If answer is yes, then list the name and Medicare identification (i.e. 26xxxx) number of the co-located provider or licensed entity.

## CERTIFICATION

We the undersigned hereby certify that we have read the foregoing application and that the statements contained therein are true and correct to the best of our knowledge, and further assure the ability and intention of the ____________________________ (legal name of corporation) to comply with Missouri statutes and regulations pertaining to hospital licensure.

___________________________  ___________________________  _______________
Chair of the Governing Body Signature  Print Name  Date

___________________________  ___________________________  _______________
Chief Executive Officer Signature  Print Name  Date

PUBLIC COST: This proposed amendment will not cost public entities more than five hundred dollars ($500) in the aggregate.

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, Dean Linneman, 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.
Governing Body 19 CSR 30-20.080

(13) Bylaws of the governing body shall provide for the selection and appointment of medical staff members based upon defined criteria and in accordance with an established procedure for processing and evaluating applications for membership. Applications for appointment and reappointment shall be in writing and shall signify agreement of the applicant to conform with bylaws of both the governing body and medical staff and to abide by professional ethical standards. Initial appointments to the medical staff shall not exceed two (2) years. Reappointments, which may be processed and approved at the discretion of the governing body on a monthly or other cyclical pattern, shall not exceed two (2) years.

(14) Bylaws of the governing body shall require that the medical staff develop and adopt medical staff bylaws and rules which shall become effective when approved by the governing body.

(15) The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments and on the basis of established requirements shall determine the privileges extended to each member of the staff and to other licensed practitioners who are granted clinical privileges.

(16) Bylaws of the governing body shall provide that notification of denial of appointment, reappointment, curtailment, suspension, revocation or modification of privileges shall be in writing and shall indicate the reason(s) for this action.

(17) The governing body shall establish mechanisms which assure the hospital's compliance with mandatory federal, state and local laws, rules and standards.

(18) Although independent licensed practitioners are not authorized membership to the medical staff, the governing body may include provisions within its bylaws to grant non-physician licensed practitioners clinical privileges, on an outpatient basis, for diagnostic and therapeutic tests and treatment. The privileges shall be within the scope and authority of each practitioner's current Missouri license and practice act.

(A) The provisions shall include a mechanism to assure that independent practitioners who provide services shall have clinical privileges delineated by the governing body or designee.

(B) The mechanism shall include criteria for a review of an independent practitioner's credentials shall be reviewed at least every two (2) years. At a minimum, the review criteria shall include documentation of a current license, relevant training and experience, and competency.

Medical Staff

19 CSR 30-20.086 Medical Staff in Hospitals

PURPOSE: This rule specifies the requirements for the organization of the medical staff in a hospital.

(1) The medical staff shall be organized, shall develop and, with the approval of the governing body, shall adopt bylaws, rules and policies governing their professional activities in the hospital.

(2) Medical staff membership shall be limited to physicians, dentists, psychologists, and podiatrists and other non-physician licensed practitioners. Non-physician practitioner medical staff appointments shall be within the scope and authority of each practitioner's current Missouri license and practice act. They shall be currently licensed to practice their respective professions in Missouri. The bylaws of the medical staff shall include the procedure to be used in processing applications for medical staff membership and the criteria for granting initial or continuing medical staff appointments and for granting initial, renewed or revised clinical privileges.

(3) No application for membership on the medical staff shall be denied based solely upon the applicant's professional degree or the school or health care facility in which the practitioner received medical, dental, psychology or podiatric schooling, postgraduate training or certification, if the schooling or postgraduate training for a physician was accredited by the American Medical Association or the American Osteopathic Association, for a dentist was accredited by the American Dental Association's Commission on Dental Accreditation, for a psychologist was accredited with accordance to Chapter 337, RSMo and for a podiatrist was accredited by the American Podiatric Medical Association. Each application for staff membership shall be considered on an individual basis with objective criteria applied equally to each applicant.

(4) Each physician, dentist, psychologist, or podiatrist or other licensed practitioner requesting staff membership shall submit a complete written application to the chief executive officer of the hospital or his designee on a form approved by the governing body. Each application shall be accompanied by evidence of education, training, professional qualifications, license and and other information required by the medical staff.
bylaws or policies.

(5) Written criteria shall be developed for privileges extended to each member of the staff and to other licensed practitioners granted clinical privileges. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff. The mechanism shall include an inquiry of the National Practitioner Data Bank. Bylaws of the medical staff shall provide for hearing and appeal procedures for the denial of reappointment and for the denial, revocation, curtailment, suspension, revocation, or other modification of clinical privileges of a member of the medical staff.

(6) Any applicant for medical staff membership or clinical privileges who is denied membership or privileges or whose completed application is not acted upon in ninety (90) calendar days of completion of verification of credentials data or a medical staff member or other practitioner whose membership or privileges are terminated, curtailed or diminished in any way shall be given in writing the reasons for the action or lack of action. The reasons shall relate to, but not be limited to, patient welfare, the objectives of the institution, the inability of the organization to provide the necessary equipment or trained staff, contractual agreements, or the conduct or competency of the applicant or medical staff member.

(7) Initial appointments to the medical staff or granting of privileges shall not exceed two (2) years. Reappointments or regranting of privileges, which may be processed and approved at the discretion of the governing body on a monthly or other cyclical pattern, shall not exceed two (2) years.

(8) The medical staff bylaws shall provide for—an outline of the medical staff organization; designation of officers, their duties and qualifications and methods of selecting the officers; committee functions; and an appeal and hearing process.

(9) The medical staff bylaws shall provide for an active staff and other categories as may be designated in the governing body bylaws. The medical staff bylaws shall describe the voting rights, attendance requirements, eligibility for holding offices or committee appointments, and any limitations or restrictions identified with location of residence or office practice for each category.

(10) The organized medical staff shall meet at intervals necessary to accomplish its required functions. A mechanism shall be established for monthly decision-making by or on behalf of the medical staff.

(11) Written minutes of medical staff meetings shall be recorded. Minutes containing peer review information shall be retained on a confidential basis in the hospital. The medical staff determine retention guidelines and guidelines for release of minutes not containing peer review materials.

(12) The medical staff as a body or through committee shall review and evaluate the quality of clinical practice of the medical staff in the hospital in accordance with the medical staff's peer review function and performance improvement plan and activities.

(13) The medical staff shall establish in its bylaws or rules criteria for the content of patients' records provisions for their timely completion and disciplinary action for noncompliance.

(14) Bylaws of the medical staff shall require that at all times at least one (1) physician member of the medical staff shall be on duty or available within a reasonable period of time for emergency service.
