

OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

April 11, 2016

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
Neil Schmidt, R.Ph., Member
Greg Teale, R.Ph., Member (participating by phone)

Committee Members Absent

Kevin Kinkade, R.Ph.,

Staff Present

Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector

Others Present

Barbara Bilek, Board Member
Sarah Wilson, Missouri Hospital Association
Julie Creach, Missouri DHSS

Chairman McClary opened the meeting at 10:04 a.m. and attendees were introduced. The Committee agreed to begin future in-person meetings at 10:00 a.m. to allow time for travel.

Agenda Item # 6: Bert McClary asked about potential sterile compounding training for DHSS surveyors. Kimberly Grinston indicated she has communicated briefly with Dean Linneman and offered the Board's assistance with surveyor training. Mr. McClary asked if the training would be limited to sterile compounding. Ms. Grinston advised the current focus is sterile compounding but other topics could be added. Mr. McClary suggested Advisory Committee members may be interested in attending the training once scheduled.

Mr. McClary asked about Board comments on DHSS' proposed hospital pharmacy rules. Ms. Grinston indicated rules were still under legal review to determine the allowed scope of Board suggestions.

Agenda Item # 2: Bert McClary asked for additional changes/suggestions to the administration by prescription order rule. Substantive rule changes/suggestions are incorporated in Attachment A. Additionally, the following discussion was held:

- Bert McClary suggested moving all requirements related to health care entities to one general section. Committee consensus to group health care entity language as suggested. Barbara Bilek asked if "medical prescription order" includes hospital protocols for administration; Bert McClary suggested the term would include protocols.
- Kimberly Grinston asked about reporting additional training on new routes of administration to the Board and indicated the Board does not collect this information for other administration settings. Neil Schmidt suggested changing section (4)(E) to require that documentation of the required training must be maintained onsite and available on request.

Greg Teale joined the meeting via conference call at 10:45 a.m. Committee discussion continued as follows:

- Neil Schmidt asked about the two-year record retention requirement. Greg Teale further asked if documents have to be in the permitted area. Kimberly Grinston indicated records might be allowed outside of the traditional permitted area, however, Katie DeBold suggested this might conflict with the Board's current offsite storage rule. Ms. Grinston indicated she would verify the Board's current requirements. Barbara Bilek asked if DHSS surveyors would review records for the previous two years. Julie Creach indicated surveyors usually review the previous year but noted OIG may want to review additional records.
- Kimberly Grinston indicated the definition of "health care entity" is much broader in the proposed administration rule than currently used in the Board's medication therapy services rules. Bert McClary stated the broader definition was intended to address administration in other hospital related settings such as long-term care facilities.
- Section (10): Kimberly Grinston asked if hospitals have training programs for pharmacist administration. Bert McClary could not answer on specific training requirements but noted that other non-pharmacy personnel are allowed to administer without additional training requirements. For example, Mr. McClary noted that Missouri law does not require nurses to complete additional training because it is presumed they are adequately trained. Neil Schmidt asked about training requirements if a nurse moves between practice settings (e.g., acute care to long-term care). Sara Wilson commented nurses do not have additional training requirements but noted the new CMS nursing standards for hospitals and ambulatory surgical centers require nurses to be trained in administering and preparing medications. Sara Wilson noted nursing training would generally be a

part of the nursing school curriculum. However, Kimberly Grinston commented administration training may not be part of the traditional pharmacy school program. Bert McClary asked if it could be assumed that administration training is required in any CMS setting.

Sara Wilson asked if the rule would remain current given that there are different models of care that are still evolving. Ms. Wilson further agreed that the proposed language assumes every hospital has a competency, training and evaluation requirement. Greg Teale noted that pharmacist Jeremy Hampton indicated in his previous Committee presentation that he could not find true administration training programs other than the current vaccine programs. Mr. Teale suggested hospitals would have to work with nursing leadership to determine what the competencies should be. Katie DeBold indicated it would help inspectors if there were minimum requirements for a hospital's training program. Bert McClary suggested changing the rule to provide a hospital-based training program must be comparable to the program required for other pharmacists. James Gray suggested that the hospital program should be similar to or include the training "components" of proposed section (7). Committee consensus to incorporate Mr. Gray's suggested language.

- Section (10)(C): Discussion was held regarding additional pharmacist training on new routes of administration. Barbara Bilek asked how a "proficient" health care provider would be defined; Sara Wilson also questioned how a hospital would document that a trainer is "proficient." Kimberly Grinston indicated the Board previously had a problem with an unlicensed nursing assistant offering an administration training program. Barbara Bilek suggested requiring training by a "licensed healthcare professional authorized to administer medication." Committee consensus to incorporate the language as suggested.

Agenda Item # 3: Bert McClary indicated he wanted to discuss DHSS rules that may affect hospital pharmacy although they may not be subject to the joint rulemaking requirements of Chapter 338, RSMo. Mr. McClary noted it is important that hospitals are aware of how the presented DHSS rules may relate to pharmacy practice. The following discussion was held:

- 19 CSR 30-20.030: Mr. McClary indicated this was originally the longest rule and commented the draft is completely new and would replace current rule language.
- 19 CSR 30-20.080: Mr. McClary indicated the proposed rule would require hospitals to give clinical privileges in order for pharmacists to perform medication therapy services. Mr. McClary cautioned it was important to differentiate between medical staff membership and clinical privileges and indicated that the granting of clinical privileges would have to be done under the medical staff process. Mr. McClary highlighted that proposed section (18) provides pharmacists can only be given privileges "on an outpatient basis." Sara Wilson commented 19 CSR 30-20.080(18) was intended to relate to practitioners who are not on the medical staff which is why it references "outpatient basis." Neil Schmidt asked if this interpretation would still require a relationship with the

hospital or if it would apply to practitioners who do not have admitting privileges. Mr. McClary commented he didn't construe 19 CSR 30-20.080(18) as relating to individuals independent from the hospital. Mr. McClary further commented the draft does not clearly distinguish between clinical privileges and medical staff privileges and recommended a clarification to directly address non-physician medical staff. Sara Wilson commented the definition of the medical staff and the governing body should be consistent. Mr. McClary agreed and suggested making this clarification for everyone.

- 19 CSR 30-20.086: Sara Wilson asked if the rule would relate to pharmacist medication administration. Bert McClary indicated the rule relates to medication protocols for monitoring patient medication therapy and ordering medication changes. Mr. McClary suggested pharmacists may need to be granted privileges to administer under the rule. James Gray asked if functioning under a medication therapy services (MTS) protocol would require privileging. Mr. McClary indicated CMS may leave this determination up to the hospital, however, under DHSS' proposed rule the pharmacist would have to be given clinical privileges. Mr. McClary further questioned if the rule should include language that addresses telehealth/telemedicine for pharmacists.

Neil Schmidt asked if pharmacists in smaller hospitals would encounter problems with getting privileges if it is not specifically allowed in DHSS' rules. Daniel Good suggested pharmacists may get resistance if pharmacist privileging is not specifically addressed in writing. James Gray commented hospitals may always choose not to grant pharmacist privileges even if addressed in rule; Bert McClary agreed. However, Neil Schmidt suggested a rule clarification may allow pharmacists to argue for inclusion. Daniel Good noted pharmacist privileging may be important for reimbursement purposes; Neil Schmidt agreed and indicated this may be a particular issue for rural hospitals. James Gray noted that the current language does not bar pharmacists from being credentialed and noted the emphasis should be on including a credentialing requirement in the medication management rule instead of adding pharmacists to the medical staff committee law.

- 19 CSR 30-20.120: Bert McClary asked what are the most high-risk medications used in the hospital that should be addressed in special rules related to administering. Committee members suggested opioids, anesthetics, chemotherapy drugs, anti-coagulants and medication on the hospital's high-risk/high-alert list. Bert McClary noted that DHSS' rule tells anesthesiologists how to administer which is different from other rules. Barbara Bilek suggested the language may be too restrictive but may be necessary.
- 19 CSR 30-20.126: Sara Wilson noted that MHA objects to the 1-on-1 observation requirement and noted that while the risk is significant current guidelines from the American Congress of Obstetricians and Gynecologists do not require 1-on-1 observation. Ms. Wilson commented Missouri's rules should not incorporate strict guidelines that may not be evidence based. Instead, Ms.

Wilson stated rule requirements should have sufficient evidentiary support and be flexible to accommodate changes in the practice of medicine and healthcare delivery. Barbara Bilek commented the scope of the rule could be enormous. Neil Schmidt suggested that high-dose medications should be addressed if oxytocin is included in the rule; Barbara Bilek agreed.

- 19 CSR 30-20.114: Barbara Bilek asked if the rule should clarify that hospitals are required to follow the stricter standard if DNR, EPA or FDA rules conflict. Bert McClary suggested DHSS should be surveying to the stricter standard.
- 19 CSR 30-20.125: Bert McClary stated the rule was never intended to include pharmacy technicians as unlicensed assistive personnel (UAP) but the rule may set a precedent. Mr. McClary noted technicians may not fully qualify as UAPs because of the requirement that UAPs provide direct patient care 25% or more of the time.
- 19 CSR 30-20.136: Barbara Bilek asked if respiratory care therapists can administer other medications and noted they may be administering sedation medication during a bronchoscopy. James Gray agreed the scope of administration for respiratory care therapists has expanded.
- Bert McClary asked for other recommended changes or comments on the rules presented. No additional suggestions were made. Bert McClary asked how/if the group's suggestions should be presented or finalized for DHSS review and suggested discussing this item at a later meeting.

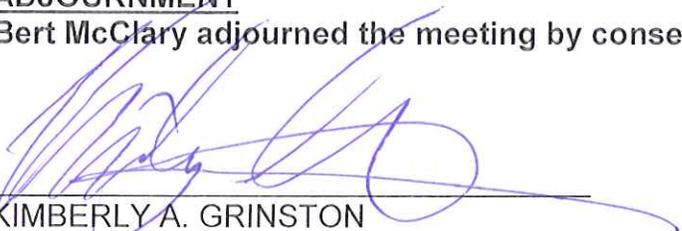
Agenda Item #5: Greg Teale commented he did not receive many responses to the webinar survey but noted that questions still exist on infusion centers. Bert McClary suggested Committee members review the webinar questions again and bring suggestions to the next meeting.

Agenda Item #4: Greg Teale commented there is still a great deal of confusion regarding allowed activities at an infusion center. Bert McClary commented the primary concern is with restrictions in the Board's rules and potential conflicts with other regulatory agencies. Bert McClary asked if the pharmacy infusion issues could be addressed in a separate Board rule that specifically addresses health care entities. Kimberly Grinston noted Board staff initially drafted a rule to address some of the hospital concerns with providing pharmacy services outside of the licensed hospital premises but noted staff did not have a clear understanding of what the actual issues were at the time. Greg Teale noted issues with nursing access to pharmacy medication was a major concern especially given that most hospitals have ways to electronically track and dispense inventory. Bert McClary asked Committee members to bring a list to the May conference call of issues related to the provision of pharmacy services at other hospital owned or affiliated locations such as infusion centers or long-term care facilities. Mr. McClary encouraged Committee members to think broadly about all affected practice settings. Sara Wilson suggested surveying MHA members to potentially identify areas of concern. Daniel Good and Greg Teale indicated they could assist MHA with survey questions.

Agenda Item #7: Neil Schmidt suggested that the Committee continue to alternate in-person and conference call meetings every other month. Committee consensus to continue meeting as suggested. The Committee agreed to meet via conference call on May 6, 2016 from 9:00-11:00 a.m. and again in Jefferson City on June 3, 2016, beginning at 10:00 a.m.

ADJOURNMENT

Bert McClary adjourned the meeting by consensus at approximately 3:49 p.m.



KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:

OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

January 11, 2016

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. The meeting was called to order by Chairman Bert McClary at 10:02 a.m. on January 11, 2016.

Committee Members Present

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

Staff Present

Kimberly Grinston, Executive Director

Others Present

Barbara Bilek, Board Member
Christian Tadrus, R.Ph., Board Member
Sharon Burnett, Missouri Hospital Association
Julie Creach, Missouri DHSS
Jeremy Hampton, Public Attendee
William Koebel, Missouri DHSS

Chairman McClary opened the meeting at 10:02 a.m. and introductions of attendees were made. Sharon Burnett from the Missouri Hospital Association (MHA) indicated she is retiring and reported Sara Wilson has been named as her replacement. Sarah Willson is the associate director of nursing and CEO of Hospice Compassus and will begin her new position with MHA on February 18, 2016.

Agenda Item # 1: Kimberly Grinston reported draft minutes from the November 6, 2015, meeting minutes have been included for review and approval. No recommended changes were suggested. **A motion was made by Greg Teale, seconded by James Gray, to approve the November 6, 2015, minutes as presented. The motion passed 4:0:1:0 with roll call vote as follows:**

James Gray – yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Kevin Kinkade - abstain

Agenda Item # 2: Bert McClary commented the Committee's proposed suggestions/changes on 19 CSR 30-20.100 will be discussed at the Board of Pharmacy's upcoming January 14, 2016, meeting and asked Committee members for any additional suggestions/changes. The substantive changes to the proposed suggestions are included in Attachment A. Additionally, the following discussion was held:

- Section (9): Bert McClary suggesting clarifying the sentence structure by modifying lines 121-122 to insert "outside of the pharmacy." Bert McClary commented that Committee members previously questioned if a hospital would be in compliance with the proposed rule and/or BNDD and DEA inventory requirements if an inventory reconciliation was conducted each time a controlled substance is used. Mr. McClary suggested the hospitals would likely be in compliance if the reconciliation is conducted at least monthly but questioned if the current language would require the inventory to be conducted on the same day. Mr. McClary also noted that the inventory required by the proposed DHSS rule would be different from the required BNDD/DEA controlled substance inventory.

Greg Teale indicated he still has concerns with the proposed language because the requirements may be confusing to hospitals. Kevin Kinkade agreed. Mr. Teale suggested issuing a FAQ to provide guidance after the rule is final. Mr. Teale also suggested that the rule focus on the biggest hospital diversion risk point which is medication stored on the floors and not medication in the pharmacy's inventory. Bert McClary generally agreed but commented pharmacy diversion is also an important risk point.

Barbara Bilek commented all schedules should be reconciled monthly and indicated a monthly inventory of every item may require significant staff resources. Greg Teale agreed and commented the proposed inventory requirements may particularly impact hospitals without a sufficient IT infrastructure. Neil Schmidt commented smaller hospitals may be required to conduct a physical count to comply.

Sharon Burnett suggested that the rule require an ongoing perpetual inventory or match CMS language which only requires that hospitals must be "capable of detecting diversion." Ms. Burnett expressed concerns that the current language could be subjectively interpreted by surveyors. Barbara Bilek questioned the definition of reconciliation as used in the draft and asked if it would include an actual count or include reconciling purchases and distributions with the current inventory using other tools/software. Barbara Bilek also suggested including a different inventory requirement for drugs stored outside of the pharmacy.

Greg Teale suggested striking lines 129-130 that require a monthly controlled inventory and commented the rule should only require that the director of pharmacy services "ensure the accountability of all controlled substances" as referenced in lines 115-117. **A motion was made by Greg Teale, seconded by James Gray, to delete section (9)(C).** No vote was taken.

After further discussion, James Gray suggested amending section (9)(C) to require that the director of pharmacy establish policies and procedures for a controlled substance diversion detection program; Sharon Burnett agreed. **A motion was made by Greg Teale, seconded by Daniel Good, to amend section (9)(C) to provide "the**

director of pharmacy shall be responsible for developing and implementing policies and procedures for a controlled substance diversion detection program.”

The motion passed 5:0:0:0 with roll call vote as follows:

James Gray – yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Kevin Kinkade - yes

- Section (11): Christian Tadrus asked if the current language was necessary given that all DEA registrants are required to report losses. Bert McClary commented the language was included to ensure inconsistencies with drug inventory are reported to the pharmacy director. James Gray indicated all hospital staff may not be reporting nurse and physician diversion issues to the director of pharmacy. Christian Tadrus asked if the rule should include language on what the director should do once reported. James Gray indicated the language was primarily intended to make other hospital personnel of the requirement to report. No changes were made.

- Section (38)(D): Bert McClary indicated the Committee previously questioned what should be done with medication after a patient expires and indicated this section was intended to establish a basic mechanism for hospitals without requiring them to take legal possession. Daniel Good suggested removing the section. Neil Schmidt suggested allowing drugs to be returned to the patient’s family upon request by the family; Daniel Good agreed. Public attendee Jeremy Hampton questioned the hospital’s liability if drugs are returned to a patient that may have overdosed. Neil Schmidt raised a similar question for patients who may have attempted suicide.

Kevin Kinkade commented that I. 587 requires that two (2) pharmacy staff members witness the drug destruction; James Gray indicated this issue should be addressed by statute not by rule. Neil Schmidt alternatively suggested including “or as otherwise authorized by law” at the end of I. 587. Greg Teale suggested alternatively allowing destruction “at the time of discharge.” Daniel Good suggested addressing the destruction requirement in the pharmacy’s policies and procedures and also suggested removing the word “legal” in I. 581. General consensus to add “in accordance with the hospital’s policies and procedures” at the end of I. 583-584 and to remove the word “legal” as suggested.

- Section (39): Bert McClary indicated Kevin Kinkade previously asked about addressing sentinel events. Mr. McClary commented that CMS rule 482.21 requires reporting of medication errors and adverse events and also requires an evaluation of attendant circumstances. Sharon Burnett indicated CMS’ rules are not clear on this topic and advised against creating additional requirements because of the constantly changing regulatory landscape. No changes were made.

- Section (2), I. 58: Neil Schmidt suggested changing “licensed with” to “licensed by.” Consensus to change as suggested.

- Section (1): Barbara Bilek commented the term “qualified pharmacist” is not defined and asked if the definition would be determined by the applicable hospital. Bert McClary indicated CMS has similar language. No changes were made.

A motion was made by Neil Schmidt, seconded by Kevin Kinkade, to approve the proposed suggestions to 19 CSR 30-20.100 with the above referenced changes. The motion passed 5:0:0:0 with roll call vote as follows:

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

Agenda Item # 1: Kimberly Grinston reported draft minutes from the December 14, 2015 minutes have been included for review and approval. No recommended changes were suggested. **A motion was made by Greg Teale, seconded by Neil Schmidt, to approve the December 14, 2015, minutes as presented. The motion passed 5:0:0:0 with roll call vote as follows:**

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

Agenda Item # 3 (Review of DHSS Hospital Pharmacy Related Rules): Bert McClary indicated the rules included in the agenda have direct or implied references to hospital pharmacy and suggested tabling the items until the Committee has the most recent revised language. Mr. McClary asked that the rules be included in the next agenda.

Agenda Item # 4 (Administration by Medical Prescription Order Rule): Bert McClary provided historical information on the rule and indicated pharmacists began asking about authorization to administer medication in a hospital circa 1988. In response, Mr. McClary indicated the Missouri Pharmacy Association worked with DHSS to provide pharmacist immunization programs. The Board of Pharmacy consequently tried to accommodate administering pharmacists but no official language was promulgated. Mr. McClary indicated CMS subsequently became more stringent and would not provide reimbursement for pharmacist administrations without specific regulatory authority. Mr. McClary indicated Chapter 338 was revised in 2007 to address this issue resulting in the current rule.

Mr. McClary stated the initial Board focus was on developing rules for administering vaccines and the concepts carried over to the administration rule. Mr. McClary commented the current rule is retail focused which resulted in comments being submitted to the Board by the Missouri Pharmacy Coalition. Overall, Mr. McClary stated the administration rule should accommodate administration in any legitimate practice setting and remove redundant record keeping requirements. Mr. McClary subsequently discussed his suggested revisions in the agenda material and recommended incorporating them into the current rule. Discussion was held.

Mr. McClary introduced Jeremy Hampton and described his experience with pharmacist administration requirements in other states. Mr. Hampton presented to the Board on the different pharmacist administration training and continuing education requirements in states such as Oregon, Washington, Louisiana and Virginia. Mr. Hampton questioned if Missouri's rule was to prescriptive.

Mr. McClary suggested reviewing each individual rule section and asked Committee members to think of all practice settings where a pharmacist might be

administering in or on behalf of a hospital such as long-term care facilities. Barbara Bilek questioned the requirements for pharmacists who are administering during a code or in other emergencies that may not be outlined in the protocol. Ms. Bilek specifically questioned procedures in a mass casualty incident where all health care practitioners may be required to assist. James Gray agreed a mass-casualty situation would be problematic under the Board's current rule and questioned if pharmacist administration should be handled as a privileging/credentialing issue.

Mr. McClary asked for comments/suggestions on the specific provisions of the rule. Discussion was held. The substantive changes of the rule are included in Attachment B.

Agenda Item # 5 (SB 808 Implementation): Bert McClary asked attendees for suggestions/comments on the implementation of SB 808. Discussion was held. Committee members asked if a Class-B pharmacy could also be licensed as a Class-J pharmacy. Bert McClary asked about the possibility of a combined inpatient/outpatient protocol. Greg Teale indicated a combined protocol could be helpful in instances where patients move from an inpatient setting to a Class B patient setting such as oncology. Committee members asked for additional information on the questions discussed during the previous joint webinar with the Board of Pharmacy, DHSS and the Missouri Hospital Association on SB 808 implementation. Kimberly Grinston indicated she would bring the previous webinar questions to the next meeting and that Board staff would be willing to do future educational webinars. Committee Consensus to review the webinar questions at a future meeting. Bert McClary asked Committee members to bring any additional webinar questions to the next meeting.

Agenda Item # 7 (Future Meeting Topics): The following future meeting topics were suggested: SB 808 implementation, technician certification, Class B & Class-J licensure issues and coordination of DHSS and Board requirements on issues such as auditing, packaging/distribution and pharmacy technician duties. Committee consensus to prioritize the DHSS rules, the proposed changes to the Board's administration by medical prescription order rule and SB 808 implementation. Bert McClary suggested reviewing the proposed pharmacist administration changes and the DHSS rules on the March conference call.

Agenda Item # 8 (Future Meeting Dates): Committee discussion was held. Committee consensus to meet on February 24, 2016, in Jefferson City and by conference call on March 2nd from noon to 2:00 p.m.

MOTION TO ADJOURN

At approximately 3:16 p.m., Greg Teale made a motion, seconded by Kevin Kinkade, to adjourn the January 11, 2016, meeting. The motion passed 5:0:0:0 with roll call vote as follows:

James Gray – yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Kevin Kinkade - yes

**KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR**

Date Approved:

1 Title 19—DEPARTMENT OF HEALTH AND
2 SENIOR SERVICES
3 Division 30—Division of Regulation and Licensure
4 Chapter 20—Hospitals
5

6 PROPOSED AMENDMENT
7

8 **19 CSR 30-20.100 Pharmacy Services and Medication Management** [*in Hospitals*]. The
9 department is amending the title of the rule and the Purpose statement; deleting sections (8),
10 (12), (20), (21), (34), (35), and (40) and renumbering thereafter; adding new sections (16), (27)
11 and (28); and amending sections (1), (2), (3), (5), (6), (7), (33), (36) through (39), and the new
12 sections (9) through (26), (29) and (32).
13

14 *PURPOSE: This amendment updates language throughout and places additional policy and procedure*
15 *development requirements regarding: pharmacy director responsibilities; pharmacy technician*
16 *personnel training records; physician review of orders and patient medication profile; medication*
17 *disposal and recall procedures; and safe handling of compounded and hazardous medication. This*
18 *amendment also clarifies the requirements associated with policy and procedures related to*
19 *medication storage and distribution systems, inventory schedules, and medication administration to*
20 *hospital patients.*
21

22 *PURPOSE: This rule establishes the requirements for pharmacy services and medication*
23 *management in a hospital to ensure optimal selection, safe use, and security of medications.*
24

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

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

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

56
57 (2) [Additional] **Sufficient** professional and supportive personnel shall be available [for] to
58 **ensure required** services are provided, including, pharmacists and intern pharmacists licensed
59 by the Missouri Board of Pharmacy. ~~Pharmacists and pharmacist interns shall be currently~~
60 ~~licensed in Missouri~~ [and all personnel shall possess the education and training necessary for
61 their responsibilities].

62
63 (3) [Support pharmacy personnel] **Pharmacy technicians** shall work under the supervision of a
64 pharmacist and shall not be assigned duties that by law must be performed by a pharmacist.
65 Interpreting medication orders, selecting, compounding, packaging, labeling and the dispensing
66 of medications by pharmacy [staff] **technicians** shall be performed under the supervision of a
67 pharmacist. Interpretation of medication orders by [support personnel] **pharmacy technicians**
68 shall be limited to order processing and shall not be of a clinical nature. **There shall be**
69 **evidence of the education, training, experience, and demonstrated competency for all duties**
70 **assigned in the pharmacy technicians' personnel records.**

71
72 (5) Space, equipment and supplies shall be available according to the scope of pharmacy services
73 provided. Office or other work space shall be available for administrative, clerical, clinical and
74 other professional services provided. All areas shall [meet standards to] maintain the safety of
75 personnel and the security and stability of medications stored, handled and dispensed.

76
77 (6) The pharmacy and its medication storage areas shall have proper conditions of sanitation,
78 temperature, light, moisture, ventilation, [and] segregation, **and security**. Refrigerated
79 medication shall be stored separate from food and other substances. The pharmacy and its
80 medication storage area shall be locked and accessible only to authorized pharmacy and
81 [supervisory] **designated** nursing personnel **according to section (20) of this rule.** [The director
82 of pharmacy services, in conjunction with nursing and administration, shall be responsible for
83 the authorization of access to the pharmacy by supervisory nursing personnel to obtain doses for
84 administering when pharmacy services are unavailable.]

85
86 (7) Medication storage areas outside of the pharmacy shall have proper conditions of sanitation,
87 temperature, light, moisture, ventilation, [and] segregation **and security**.

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

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

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

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

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

100

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

105

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

114

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

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

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

129 ~~(C) Inventories of controlled substances in the pharmacy shall be reconciled at least~~
130 ~~monthly.~~ The director of pharmacy shall be responsible for developing and implementing
131 policies and procedures for a controlled substance diversion detection program.
132

133

134 *[(11)]* **(10)** Controlled *[substance storage areas in the pharmacy]* substances shall be
135 *[separately]* stored in locked *[and]* compartments separate from non-controlled substances.
136 **Controlled substances in the pharmacy shall be** accessible only to authorized pharmacy staff.
137 *[Reserve supplies of all controlled substances in the pharmacy shall be locked.]* Controlled
[substance storage areas] substances outside the pharmacy shall be *[separately locked and]*

138 accessible only to persons authorized to administer *[them]* **controlled substances** and to
139 authorized pharmacy staff.

140
141 *[(12) Authorization of access to controlled substance storage areas outside of the pharmacy,*
142 *shall be established by the director of pharmacy services in conjunction with nursing and*
143 *administration. The distribution and accountability of keys, magnetic cards, electronic codes or*
144 *other mechanical and electronic devices that allow access to such areas shall occur according to*
145 *the hospital's policies and procedures.]*

146
147 *[(13)]* **(11)** All variances, **discrepancies, inconsistencies or non-compliance** involving
148 controlled substances---including inventory, **audits**, security, record keeping, administration, and
149 disposal---shall be reported to the director of pharmacy services for review and investigation.
150 *[Loss, diversion, abuse or misuse of medications shall be reported to the director of pharmacy*
151 *services, administration, and local, state and federal authorities as appropriate.]*

152
153 *[(14) The provision of pharmacy services in the event of a disaster, removal from use of*
154 *medications]* **(12) Medications** subject to *[product]* recall *[and reporting of manufacturer drug*
155 *problems shall occur according to the hospital's policies and procedures]* **shall be handled**
156 **through a medication recall program that includes removal of the product from patient**
157 **care and inventory sites, quarantine of the recalled product and maintenance of records.**
158 **Where the risk of harm is significant, patients receiving the medication and the prescriber**
159 **or authorizing practitioner shall be notified.**

160
161 *[(15)]* **(13)** Compounding and repackaging of **sterile and non-sterile** medications in the
162 pharmacy shall be *[done by pharmacy personnel]* **performed** under the supervision of a
163 pharmacist. *[Those]* **Compounded** medications shall be labeled with the medication name*[,];*
164 strength*[,];* lot number, **as appropriate**; *[expiration]* **beyond use date**; and other pertinent
165 information. *[Record keeping]* **Records shall be maintained** and quality control, including end-
166 product testing, **shall be performed** when appropriate *[,shall occur according to the hospital's*
167 *policies and procedures].*

168
169 *[(16)]* **(14)** *[Compounding, repackaging or relabeling of]* **The director of pharmacy services**
170 **shall determine when non-pharmacy personnel may compound, repackage, or re-label**
171 **sterile and non-sterile** medications *[by non-pharmacy personnel shall occur according to the*
172 *hospital's policies and procedures. Medications]* **Except in approved circumstances,**
173 **medications compounded by non-pharmacy personnel** shall be administered routinely by the
174 person who prepared them*[,]* and preparation shall occur just prior to administration *[except in*
175 *circumstances approved by the director of pharmacy, nursing and administration. Compounded*
176 *sterile medications for parenteral administration prepared by non-pharmacy personnel shall not*
177 *be administered beyond twenty-four (24) hours of preparation.]* Labeling shall include the
178 patient's name*[, where]* **when** appropriate, medication name, strength, beyond use date **when**
179 **appropriate**, identity of the person preparing and other pertinent information.

180
181 *[(17)]* **(15)** Compounded sterile medications shall be *[routinely]* prepared *[in a suitably*
182 *segregated area in a Class 100 environment by pharmacy personnel. Preparation by*
183 *nonpharmacy personnel shall occur only in specific areas or in situations when immediate*

184 preparation is necessary and pharmacy personnel are unavailable and shall occur according to
185 policies and procedures. All compounded cytotoxic/hazardous medications shall be prepared in
186 a suitably segregated area in a Class II biological safety cabinet or vertical airflow hood. The
187 preparation, handling, administration and disposal of sterile or cytotoxic/hazardous medications
188 shall occur according to policies and procedures including: orientation and training of
189 personnel, aseptic technique, equipment, operating requirements, environmental considerations,
190 attire, preparation of parenteral medications, preparation of cytotoxic/hazardous medications,
191 access to emergency spill supplies, special procedures/products, sterilization, extemporaneous
192 preparations and quality control.], **handled, administered and disposed of according to**
193 **sections (17) and (28) of this rule and as follows:**

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

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

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

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

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

210

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

217

218 [(18)] (17) Radiopharmaceuticals shall be acquired, stored, handled, prepared, packaged,
219 labeled, **distributed**, administered and disposed of [*according to the hospital's policies and*
220 *procedures and*] only by or under the supervision of [*personnel who are certified by the*] a
221 **pharmacist or physician who is a Nuclear Regulatory Commission (NRC) authorized user.**
222 **The NRC authorized supervising pharmacist or physician shall consult with the director of**
223 **pharmacy to ensure that radiopharmaceuticals are used consistent with the provisions of**
224 **this rule while recognizing the requirements for physically handling radiopharmaceuticals**
225 **only by NRC authorized personnel.**

226

227 [(19)] (18) A medication ~~profile record~~ **shall be maintained** for each patient.

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

Comment [GK1]: The final rule should cite the most current version of USP.

230 | 1. Entries to a pharmacy medication ~~profile~~ record shall be made only by the
231 | prescriber, a pharmacist, or a pharmacy technician. Each entry by a non-pharmacist shall
232 | be reviewed and approved by the pharmacist prior to administering, except as allowed in
233 | subsection (C) of this section.

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

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

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

243 | 1. In an urgent situation;

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

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

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

252 |
253 | [*(20) Medications shall be dispensed only upon the order of an authorized prescriber. with the*
254 | *exception of influenza and pneumococcal polysaccharide vaccines, which may be administered*
255 | *per physician-approved policy/protocol after an assessment for contraindications, and only*
256 | *dispensed by or under the supervision of the pharmacist.*

257 |
258 | [*(21) All medications dispensed for administration to a specific patient shall be labeled with the*
259 | *patient name, drug name, strength, expiration date and, when applicable, the lot number and*
260 | *other pertinent information.*]

261 |
262 | [(22)] (19) The medication distribution system shall provide safety and accountability for all
263 | medications, include unit of use and ready to administer packaging, and meet current standards
264 | of practice. **Distribution systems may include, but are not limited to, traditional unit dose**
265 | **systems and electronic automated systems.**

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

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

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

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

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

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

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

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

291

292 [(23)] (20) To prevent unnecessary entry to the pharmacy, a locked supply of routinely used
293 medications shall be available for access by authorized personnel when the pharmacist is
294 unavailable. Removal of medications from the pharmacy by ~~trained~~ authorized [*supervisory*]
295 nursing personnel, documentation of medications removed, restricted and unrestricted
296 medication removal, later review of medication orders by the pharmacist, and documented audits
297 of medications [*removal*] **removed** shall occur according to the hospital's policies and
298 procedures. [*The nurse shall remove only amounts necessary for administering until the*
299 *pharmacist is available.*]

300

301 [(24)] (21) Floor stock medications **are medications that are not dispensed from the**
302 **pharmacy for a specific patient or do not require pharmacist prospective order**
303 **review/approval. Floor stock medications** shall be limited to **approved** emergency and
304 nonemergency medications [*which are authorized by the director of pharmacy services in*
305 *conjunction with nursing and administration. The criteria, utilization and monitoring of*
306 *emergency and non-emergency floor stock medications shall occur according to the hospital's*
307 *policies and procedures*]. Supplies of emergency medications shall be available in designated
308 areas. **Non-emergency floor stock medications shall be available only in limited quantities**
309 **as determined by the director of pharmacy.**

310

311 [(25)] (22) All medication storage areas in the hospital shall be inspected at least monthly by a
312 pharmacist or ~~his or her~~ *designee, according to the hospital's policies and procedures*
313 ~~pharmacy technician~~. **Expired, mislabeled or otherwise unusable medications shall not be**
314 **available for patient use.**

315

316 [(26)] (23) The pharmacist shall be responsible for the acquisition, inventory control,
317 dispensing, distribution and related documentation requirements of investigational medications
318 [*according to the hospital's policies and procedures*]. A copy of the investigational protocol
319 shall be available [*in the pharmacy*] to all health care providers who prescribe [*or*], administer,

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

322

323 [(27)] **(24)** Sample medications shall be received and distributed **only** by the pharmacy
324 [according to the hospital's policies and procedures].

325

326 [(28)] **(25)** Dispensing of medications by the pharmacist [to] **for use by** patients [who are
327 discharged from the hospital or who are outpatients] **outside of the hospital** shall be in
328 compliance with [4 CSR 220] [Chapter 338, RSMo, and 20 CSR 2220](#).

329

330 [(29) Persons] **(26) Medications may be provided to patients for use outside the hospital,**
331 **by persons** other than the pharmacist. [may provide medications to patients leaving the hospital
332 only when prescription services from a pharmacy are not reasonably available. Medications]

333 **(A) When the patient is a registered patient of the emergency department or is being**
334 **discharged from the hospital:**

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

337 **a.** circumstances when medications may be provided[.];

338 **b.** practitioners authorized to order[.];

339 **c.** specific medications [and];

340 **d.** limited quantities[.];

341 **e.** prepackaging and labeling by the pharmacist[.];

342 **f.** final labeling to facilitate correct administration[.];

343 **g.** delivery[.];

344 **h.** counseling; and

345 **i.** a transaction record.

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

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

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

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

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

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

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

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

368 2. When the automated dispensing system is controlled by the pharmacy according to
369 regulations of the Missouri Board of Pharmacy, including, but not limited to 20 CSR 2220-
370 2.900, it may be used at all times the pharmacist is on duty.

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

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

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

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

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

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

387 (a) The medication is necessary for administration during transport of the patient;
388 (b) The quantity of controlled substance sent is documented in the patient's medical
389 record by the person sending the medication; and
390 (c) The pharmacy is notified that the medication was sent with the patient.

391

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

399

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

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

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

406

407 [(30)] (29) Current medication information resources shall be [maintained] accessible in the
408 pharmacy and patient care areas. The pharmacist shall provide medication information to the
409 hospital staff as requested.

410

411 | [(31)] **(30)** The director of pharmacy services or his or her pharmacist designee shall be an
412 active member of the pharmacy and therapeutics committee or its equivalent, which shall advise
413 the medical staff on all medication matters. A formulary shall be established which includes
414 medications based on an objective evaluation of their relative therapeutic merits, safety and cost
415 and shall be reviewed and revised on a continual basis.

416
417 **(31)** A medication use evaluation program shall be established which evaluates the use of
418 selected medications to ensure that they are used appropriately, safely and effectively. Follow-up
419 educational information shall be provided and appropriate interventions implemented if needed
420 in response to evaluation findings.

421
422 (32) The pharmacist shall be available to [*participate*] **consult** with medical and nursing staff
423 [*regarding decisions about*] **to ensure appropriate** medication use for individual patients,
424 including **but not limited to:** [*not to use medication therapy;*] medication selection, dosages,
425 routes and methods of administration; medication therapy monitoring; provision of medication-
426 related information; and counseling to individual patients. [*The pharmacist or designee shall*
427 *personally offer to provide medication counseling when discharge or outpatient prescriptions*
428 *are filled. The pharmacist shall provide requested counseling.*]

429
430 (33) [*Medication orders*] **Medications** shall be [*initiated or modified*] **ordered** only by
431 practitioners who have independent statutory authority to prescribe or who are [*legally given*
432 *authority*] **authorized** to order medications **by their professional licensing agency as provided**
433 **by state law.** [*That authority may be given through an arrangement with a practitioner who has*
434 *independent statutory authority to prescribe and who is a medical staff member. The*]

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

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

445 **~~(C) Pharmacist medication therapy services protocols shall:~~**
446 **~~1. Be authorized pursuant to a document granting hospital privileges to the~~**
447 **~~pharmacist which is signed by the pharmacist;~~**
448 **~~2. Include the minimum education, training and other qualifications that must be~~**
449 **~~met by the pharmacist; and~~**
450 **~~3. Be approved by the medical staff.~~**
451

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

467 (A) The hospital shall:

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

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

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

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

480 (B) Such orders and protocols:

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

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

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

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

489
490 (35) *[Medication orders shall be written according to policies and procedures and those written*
491 *by persons who do not have independent statutory authority to prescribe shall be included in the*
492 *quality improvement program.] With the exception of approved standing orders and*
493 *protocols, and approved vaccines which may be administered according to policy of the*
494 *medical staff after an assessment of contraindications, medications shall be administered*
495 *only upon the order of a person authorized to prescribe or order medications.*

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

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

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

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

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

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

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

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

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

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

517
518 (36) Automatic stop orders for all medications shall be established and shall include a procedure
519 to notify the prescriber of an impending stop order. A maximum stop order shall be effective for
520 all medications which do not have a shorter stop order. *[Automatic stop orders are not required*
521 *when the pharmacist continuously monitors medications to ensure that they are not*
522 *inappropriately continued.]*

523
524 (37) Medications shall be administered only by *[persons]* **practitioners** who have statutory
525 authority to administer or **persons** who *[have]* **are authorized by the medical staff and meet**
526 **the following:**

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

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

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

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

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

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

536 **3. Patient assessment and monitoring;**

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

539 **5. Cardiopulmonary resuscitation;**

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

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

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

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

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

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

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

561

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

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

568 (B) **Controlled substances**

569 1. **Shall be inventoried at a minimum upon admission and discharge by a person**
570 **who is authorized to administer controlled substances or by authorized**
571 **pharmacy personnel and a copy of each inventory shall be provided to the**
572 **pharmacy;**

573 2. **Shall be security sealed and stored in a locked area accessible only to**
574 **individuals authorized to administer controlled substances or to authorized**
575 **pharmacy personnel; and**

576 3. **Inventory at the time of discharge shall include a receipt signature of the**
577 **patient or the patient's representative.**

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

582 (D) Medications in the ~~legal~~ possession of the patient shall be returned to the patient or
583 the patient's representative ~~at the time of discharge except when the patient has expired~~ in
584 accordance with the hospital's policies and procedures. When medications are not
585 returned to the patient or the patient's representative, they shall be transferred to the
586 pharmacy, documented and destroyed. Controlled substances shall be inventoried and
587 destroyed by two (2) authorized pharmacy personnel or as otherwise authorized by law.
588

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

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

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

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

601
602 *[(40) Medication incidents, including medication errors shall be reported to the prescriber and*
603 *the appropriate manager. Medication incidents shall be reported to the appropriate committee.*
604 *Adverse medication reactions shall be reported to the prescriber and the director of the*
605 *pharmacy services. The medication administered and medication reaction shall be recorded in*
606 *the patient's medical record. Adverse medication reactions shall be reviewed by the pharmacy*
607 *and therapeutics committee, and other medical or administrative committees when appropriate.]*

608
609 *AUTHORITY: sections [192.006 and] 197.080], RSMo 2000] and 197.154, RSMo Supp. [2007]*
610 *2014.* This rule previously filed as 19 CSR 30-20.021(3)(G). Original rule filed June 27, 2007,*
611 *effective Feb. 29, 2008. *Original authority: 192.006, RSMo 1993, amended 1995; 197.080,*
612 *RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

613
614 *PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions*
615 *more than five hundred dollars (\$500) annually.*

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

618 *NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to*
619 *this proposed amendment with the Missouri Department of Health and Senior Services, Division*
620 *of Regulation and Licensure, Jeanne Serra, Division Director, PO Box 570, Jefferson City, MO*
621 *65102-0570. To be considered, comments must be received within thirty (30) days after*
622 *publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

623
624

**Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care
Standards**

20 CSR 2220-6.040 Administration by Medical Prescription Order

PURPOSE: This rule establishes procedures for pharmacists to administer drugs and ~~devices~~ vaccines pursuant to medical prescription orders.

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices, including vaccines, pursuant to a medical prescription order.

(2) Definition. The following definitions shall apply for purposes of this rule:

(1) "Health Care Entity"- A health care entity shall include any entity or organization, other than a pharmacy licensed under Chapter 338, RSMo, that is licensed or certified by the state or federal government to provide health care services and that is required to maintain patient medical records by state or federal law.

(2) "Medical Prescription Order"- A lawful order for medications or devices issued by an authorized practitioner within the scope of his/her professional practice which is to be dispensed or administered to the ultimate user or recipient.

~~(2)~~(3) The pharmacist may not delegate the administration to another person, except to an ~~pharmacist intern~~ intern pharmacist who has met the qualifications under subsections ~~(3)(B), (C), and (E)~~ (4)(B) - (D) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order. The pharmacist and pharmacist intern shall maintain proof of the intern's compliance with this subsection.

~~(3)~~(4) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the state Board of Pharmacy. To file a Notification of Intent, a pharmacist must—

(A) Hold a current, ~~unrestricted~~ license to practice pharmacy in this state;

Comment [GK1]: Should we include the definition from 338.165(5):

(5) "Medication order", an order for a legend drug or device that is:
(a) Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee; and
(b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;

(B) Hold a current ~~provider-level cardiopulmonary resuscitation (CPR)~~ Basic Life Support certification (BLS) issued by the American Heart Association, ~~or~~ the American Red Cross or an equivalent organization. The certificate program must include a live training component;

(C) Successfully complete a certificate program in the administration of drugs ~~accredited provided~~ by: ~~the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy~~ (1) a continuing education provider accredited by the Accreditation Council for Pharmacy Education (ACPE) or (2) a governmental entity, healthcare professional organization or education/institution approved by the Board. To obtain Board approval, the training program must [be taught by qualified instructors/a licensed healthcare professional and] provide instruction in: . ~~The certificate program must cover a~~

1. Physiology and techniques for routes of administration which must include hands-on training in all routes of administration the pharmacist utilizes;
2. Drug storage and handling;
3. Informed consent requirements, if applicable;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal; and
6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks; and

(D) ~~Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;~~

~~(E) Maintain documentation of the above requirements; and~~

~~(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.~~

~~(4)~~ (5) General Requirements.

(A) A pharmacist shall administer drugs in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC), if applicable, or and in accordance with manufacturer's guidelines. In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs by medical prescription order, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. ~~The manual~~ Policies and procedures shall be reviewed annually by the pharmacist-in-charge and must be available for inspection by the State Board of Pharmacy or authorized representative. Documentation of the annual review must be maintained in the pharmacy's records. At a minimum, the required policies and procedures must include provisions governing:

1. Drug administration procedures, including, authorized routes of administration,
2. Drug storage;
3. Pre- and post- administration assessment and counseling, including, providing vaccine information statements when applicable;
4. Biohazard waste disposal and disposal of used/contaminated supplies;
5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.

(D) Drugs must be stored within the manufacturer's labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.

(E) Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

~~(5)~~ (6) Requirements of Medical Prescription Order. The medical prescription order from a ~~licensed prescriber~~ an authorized practitioner must contain at a minimum the following:

- (A) The name of the ~~licensed prescriber~~ authorized practitioner issuing the order;
- (B) The name of the patient to receive the drug;
- (C) The name of the drug and dose to be administered;
- (D) The route of administration;
- (E) The date of the original order; and
- (F) The date or schedule, if any, of each subsequent administration; ~~and~~
- ~~(G) A statement that the drug is to be administered by a pharmacist.~~

~~(6)~~ (7) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy.

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, ~~lot number~~, and expiration date of the drug. The lot number shall be documented and recorded for vaccines and biologics;
4. For vaccines, the name and address of the patient's primary health care provider, as identified by the patient. The pharmacist shall document in the patient's immunization record if a patient's primary health care provider is unknown or not designated by the patient;
5. The ~~name or identifiable initials~~ identity of the administering pharmacist. If administered by an intern pharmacist, the identity of the intern and the supervising pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable;
7. A patient's refusal or failure to remain in or return to the pharmacy as requested after vaccine administration to observe any adverse reactions; and
8. Written or electronic documentation that required notifications have been sent.

(B) All records required by this regulation shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives.

~~(7)~~ (8) Notification Requirements.

Comment [GK2]: The Advisory Committee suggested the rule should also allow offsite storage. KIM QUESTION: Was this suggestion for all entities/pharmacists or just hospitals?

(A) A pharmacist administering ~~drugs~~ a vaccine pursuant to a medical prescription order shall notify the ~~prescriber within seventy-two (72) hours~~ patient's primary health care provider, if provided by the patient, within fourteen (14) days after administration of the following:

1. The identity of the patient;
2. The identity of the ~~drug~~ vaccine administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) In the event of any adverse event or reaction experienced by the patient following administration of a drug, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. The prescriber may not opt of adverse notification requirements.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

(D) Documentation that the required notifications have been sent must be kept at the pharmacy or other authorized location where the prescription order is maintained.

(9) Notification of Intent Refiling. A Notification of Intent to administer drugs by medical prescription order shall be refiled with the state board of pharmacy biennially along with the pharmacist's Missouri pharmacist license. To refile, pharmacist's must:

(A) Hold a current Basic Life Support certification issued by the American Heart Association or the American Red Cross or an equivalent organization. The certification program must include a live training component; and

(B) Have successfully completed four (4) hours of continuing education (0.4 CEU) related to medication administration. The required continuing education (CE) shall be governed by the rules of the state Board of Pharmacy governing pharmacist CE and may be used to satisfy the pharmacist's biennial pharmacist renewal CE requirements. The initial training program required by subsection (4) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within twelve (12) months prior to refiling the pharmacist's Notification of Intent.

(10) Administration in a Health Care Entity- Pharmacists administering medication in a health care entity shall comply with the requirements of this rule with the following exceptions:

(1) A pharmacist shall be deemed in compliance with the requirements of sections (5), (6), (7) and (8) of this rule if the pharmacist administers medication for or on behalf of a health care entity and the administration is lawfully recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law.

(2) In lieu of completing a certificate program in the administration of medication as required by section (3) of this rule, pharmacists administering in a health care entity shall be trained in administration and meet all competency, training and evaluation requirements required by the Missouri Department of Health and Senior Services.

(3) If a pharmacist administering medication in a health care entity wishes to administer medications by a route of administration not included in the original certification program, the pharmacist shall [first] be trained in the techniques of that route of administration by a health care practitioner who is proficient in that route of administration. The pharmacist shall provide the Board with a written statement from the health care practitioner attesting that both the health care practitioner and the pharmacist are proficient in that route of administration.

(4) A pharmacist shall administer vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC), if applicable, and in accordance with manufacturer's guidelines. In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

(5) The policy and procedure review required by section (5) shall be performed by the pharmacist-in-charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the health care entity responsible for reviewing clinical practices.

(6) The records required by this section may be securely stored offsite at a location designated by the health-care entity, provided records must be produced as provided in section (11) of this rule.

(11) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation as requested by the Board or the Board's authorized designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a

Comment [GK3]: Was this language intended for all pharmacists or just for pharmacists administering in a health care entity?

request from the Board and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and section 338.010.1, RSMo Supp. 2007. Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

February 24, 2016

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
Kevin Kinkade, R.Ph., Member
Neil Schmidt, R.Ph., Member
Greg Teale, R.Ph., Member

Staff Present

Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector

Others Present

Barbara Bilek, Board Member
Christian Tadrus, R.Ph., Board Member
Sarah Wilson, Missouri Hospital Association
Julie Creach, Missouri DHSS

Chairman McClary opened the meeting at 8:34 a.m. and introductions of attendees were made. Sarah Wilson was introduced as the new Vice-President of Clinical and Regulatory Affairs for the Missouri Hospital Association (MHA). Daniel Good and Colby Grove joined the meeting at approximately 8:44 a.m. Mr. McClary announced Colby Grove has been appointed to the Committee as the official Missouri Pharmacy Association representative. Mr. Grove introduced himself and indicated he is currently employed by Walgreens pharmacy.

Agenda Item # 1: The Committee reviewed the suggested Board changes to the proposal included in the agenda materials. James Gray asked if the proposal should reference USP Chapter 795. Bert McClary indicated it was a good suggestion but may need further vetting/discussion. Committee consensus to inform the Board that the suggested changes were reviewed by the Committee and no objections were raised.

Agenda Item # 2 & #3: Bert McClary indicated these items would be discussed on the March 2016 conference call.

Agenda Item # 4: Bert McClary indicated the Board of Pharmacy and DHSS hosted a webinar in conjunction with MHA after SB 808 was enacted to provide additional compliance information, however, the recording of the webinar was lost due to technical issues. Tom Glenski reviewed the slides during the meeting from the original webinar. Additionally, the following discussion was held:

- Tom Glenski commented that the “licensed hospital” generally does not include entities on the same campus or under the same provider number unless considered as part of the hospital license by DHSS. A question was raised regarding multi-purpose licenses. Mr. Glenski indicated multi-purpose licenses are generally considered as one hospital unless determined otherwise by DHSS. Bert McClary provided additional history on the definition of the hospital premises and indicated nursing homes and long-term units could be included under the hospital license if they are named with DHSS as part of the hospital premises.
- Tom Glenski discussed the Class B/drug-distributor license exemption language in SB 808 and indicated the Board’s revised drug distributor rule is somewhat broader. Mr. Glenski indicated the drug distributor exemption only applies to medication leaving the hospital and does not exempt facility shipments to the hospital. Bert McClary asked about distributions within a campus to an ambulance service that may be owned by a separate party. Tom Glenski indicated distributions to separately owned ambulance services may not qualify for the exemption. Mr. McClary indicated the previous policy was that supplying an ambulance service was not considered distribution to an outside entity if the ambulance service was based out of the hospital. Mr. McClary also suggested dispensing to an ambulance service could be considered emergency dispensing. Further discussion was held. Neil Schmidt asked if this issue raised Robinson-Patman concerns.
- Tom Glenski discussed the definition of inpatient dispensing and generally defined it as a drug prepared and administered to a patient within the DHSS licensed hospital premises regardless of billing status. Further discussion was held. Mr. Glenski reported SB 808 would now allow both inpatient and outpatient dispensing at the same location. Barbara Bilek and Neil Schmidt indicated current 340(B) requirements may impact commingling of inpatient and outpatient dispensing.
- Tom Glenski indicated the Class B pharmacy area would generally consist of the area inspected by the Board during the initial inspection and indicated the expanded Class B language would allow qualifying satellite pharmacies to be licensed as a Class B pharmacy.
- Bert McClary asked if additional rule language should be developed to address satellite pharmacies or instances where pharmacists are used to assist in dispensing in auxiliary locations such as infusion clinics, physician clinics and hospital emergency departments when pharmacy services are not available. Barbara Bilek indicated CMS may require pharmacist participation in these

alternative locations which can be complicated under current Board rules. Greg Teale strongly suggested that the Committee and the Board consider accommodating infusion clinics as the current regulatory environment has become a significant challenge. Mr. Teale indicated the Board should encourage pharmacist participation in these settings to protect the public. At a minimum, Mr. Teale, Neil Schmidt and Barbara Bilek suggested aligning the Board's rules/statutes with current DHSS, Joint Commission and CMS standards. Bert McClary asked that staff add the regulation of satellite pharmacies/alternative hospital practice settings to a future agenda for additional discussion and suggested the Committee could be instrumental in educating the Board about the unique differences in hospital practice. Committee members also asked that the Board clarify what is the pharmacy permit area.

- Tom Glenski indicated he's been asked about access to a Class B pharmacy by other practitioners and indicated these practitioners may need to be registered as technicians. Bert McClary and James Gray indicated this may not be practical for hospitals and asked how the language could be amended to accommodate hospital practice. Tom Glenski suggested that Committee Members draft rule language for the Board's review.
- Bert McClary asked about automated dispensing systems in the emergency department that may be used to provide patient take home medications. Mr. McClary suggested there may be two options: (1) conduct the activity under full Board regulation/licensure or (2) treat this activity as an extension of medication administration and address it as a take-home medication supply cart that is accessed by physicians and nurses. Tom Glenski remarked these systems are not set-up as pharmacy supervised systems and asked if this was really physician dispensing. Tom Glenski questioned the amount of medication allowed and suggested that DHSS rules may prohibit dispensing a full course of therapy.
- Discussion was held regarding the current medication therapy services (MTS) requirements. Greg Teale suggested that the Committee review the MTS requirements for infusion clinics. Jim Gray suggested revising the current rule to allow a single group MTS protocol when MTS is done under the technical hospital system but not on the hospital premises. Mr. Teale asked if an advanced practice provider can initiate an MTS protocol. James Gray indicated the current statute only allows initiation by a physician. Questions were also raised regarding MTS services by contracted staff. Bert McClary suggested possibly developing a future MTS guidance document. Mr. McClary also indicated CMS has issued guidance on non-physician privileging/credentialing issues.
- Committee consensus to consider a potential rule for Class B hospital related issues. Bert McClary suggested reviewing the following issues as part of the rule consideration: (1) remotely located infusion centers and the current restrictions on filling/distributing orders, (2) emergency department dispensing, (3) access to clinic pharmacies by nursing staff and (4) an exemption that would allow drug distribution from other hospital related locations/clinics.

- Tom Glenski asked the MSHP representative to solicit webinar questions from MSHP's membership. Tom also cautioned attendees that some offsite Class B pharmacies are using their internal ordering system to dispense controlled substances. Mr. Glenski cautioned that hospitals would need to follow DEA rules on electronic ordering.

Agenda Item # 7 & # 8: The following future topics were suggested by Board members: regulation of pharmacy technicians within a hospital, SB 808 implementation issues, state regulation of infusion centers and special rules for Class B pharmacies. Additionally, the following discussion was held on the regulation of pharmacy technicians:

- Christian Tadrus asked for suggestions on participants for the Board's pharmacy technician working group. Mr. Tadrus indicated community pharmacies are not opposed to discussing technician qualifications but indicated significant questions still remain about feasibility/value of potential approaches. James Gray commented on advances in remote supervision and suggested leveraging technology to more fully utilize pharmacist expertise. Mr. Gray also commented remote technician supervision may not be appropriate in community pharmacy at this time but may be ripe for hospitals. Barbara Bilek cautioned small hospitals would have to afford the Board's decision regarding remote/electronic supervision. James Gray suggested a rule could provide a clearer path for leveraging technology when operating within an organized healthcare system. Greg Teale suggested that the committee consider a tech-check-tech proposal and indicated this would significantly advance efficiency and operational processes in hospitals.
- Christian Tadrus asked the Committee what technician qualification standards are needed to protect the public. Kimberly Grinston indicated the topic was discussed in a recent state regulator meeting where it was suggested that technician certification was a way to ensure a quality job market. Barbara Bilek indicated technician certification does not guarantee a better work ethic.
- Sarah Wilson asked if pharmacy technicians fall under the unlicensed assisting personnel (UAP) rules. Bert McClary indicated it was unlikely because 25% of their activities may not be directly related to patient care. Greg Teale indicated some hospitals may be using unregistered technicians in parts of the hospital under DHSS' authority. Bert McClary suggested this should not be an acceptable practice.
- Additional discussion was held regarding final verification by a pharmacist of patient orders. James Gray indicated final pharmacist verification may not be happening in some critical access hospitals with limited staff. Neil Schmidt asked about hospitals with drug rooms. Greg Teale indicated other states are using technology to allow alternative means of pharmacist supervision and verification. Mr. Teale specifically indicated Wisconsin allows technicians to dispense chemotherapy products with a pharmacist remotely supervising and signing off on their work. Mr. Teale suggested that Missouri should be progressive and

consider similar models. Bert McClary cautioned against expanding technician duties/roles until the training issues are addressed.

The Committee agreed to meet via conference call on March 2, 2016, and again in Jefferson City on April 11, 2016.

ADJOURNMENT

Bert McClary adjourned the meeting by consensus at approximately 2:36 p.m.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:

A Review of Senate Bill 808 and the Revised Class B Hospital Pharmacy Permit

**Missouri
Board of Pharmacy**



**Missouri
Department of Health
and Senior Services**

January 23, 2015

Presenters

Missouri Board of Pharmacy

- Kimberly Grinston, J.D. – Executive Director
- Tom Glenski, R.Ph. – Chief Inspector

Missouri Department of Health and Senior Services

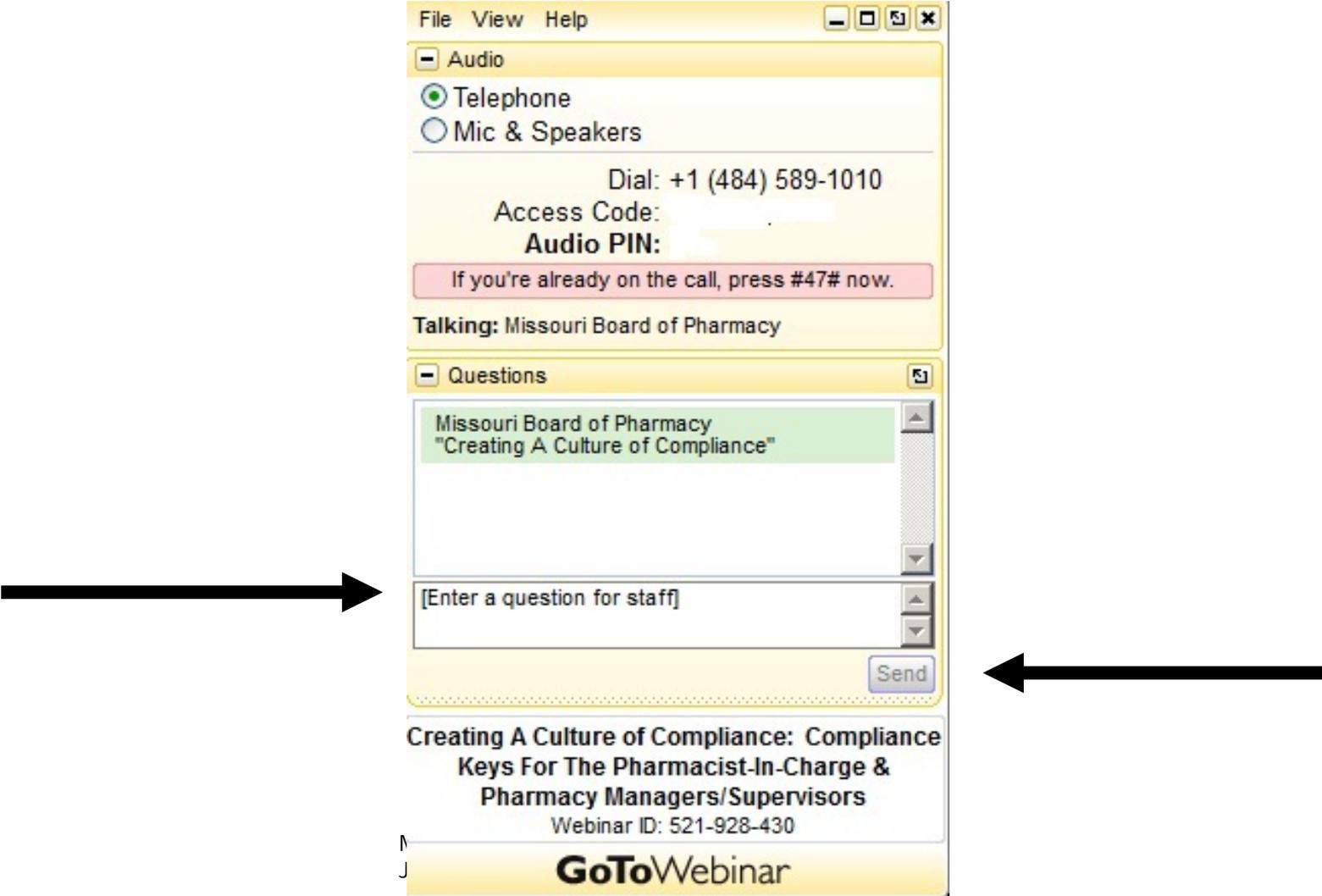
- Dean Linneman, - Deputy Division Director
Division of Regulation and Licensure

Program Objectives

- Review Senate Bill 808 effects on the practice of pharmacy in hospital settings
- Explain the revised Class B Hospital Pharmacy permit
- Answer related questions

No pharmacy continuing education credit is being offered for this program

How to Ask a Question



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Talking: Missouri Board of Pharmacy

Questions

Missouri Board of Pharmacy
"Creating A Culture of Compliance"

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Creating A Culture of Compliance: Compliance
Keys For The Pharmacist-In-Charge &
Pharmacy Managers/Supervisors
Webinar ID: 521-928-430

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SB 808

- Revised Class B Hospital ~~Outpatient~~ Pharmacy
 - Owned, managed or operated by a hospital
 - Includes pharmacy located in a clinic or facility under common control, management, or ownership of the same hospital or hospital system

SB 808

Definitions:

- "Hospital", a hospital as defined in section 197.020
- "Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system

SB 808

- Does not change jurisdiction of either DHSS or BOP within a hospital
- Hospital pharmacies solely providing drugs for patients within the hospital still require no BOP license
- Joint rulemaking between DHSS and BOP governing medication distribution and MTS by a pharmacist within a hospital
- Gives BOP authority to investigate complaints about individual BOP licensees within a hospital

SB 808

- Require BOP MTS certificate for pharmacists performing MTS within hospital
- No BOP drug distributor license required to distribute drugs from Class B permit to hospital clinic or facility for patient care

SB 808

- Allows prescription labeling by unique identifier instead of sequential number
- Allows use of orders versus prescriptions by Class B pharmacy
 - Did **not** address generic substitution of such orders
 - Seek guidance from your legal counsel concerning substitution

SB 808

"Medication order", an order for a legend drug or device that is:

(a) Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee; and

(b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;

"Patient", an individual receiving medical diagnosis, treatment, or care at a hospital or a hospital clinic or facility.

SB 808

Creation of advisory committee to review and make recommendations to all BOP/DHSS joint rules

- Seven members, designated by
 - MHA (2)
 - MSHP (1)
 - MPA (1)
 - DHSS (2)
 - BOP (1)
- BOP awaiting designations

Class B Hospital Pharmacy

- No longer limited to DHSS licensed premise
- Can be off-site hospital clinic or facility
- Can use orders instead of two-line prescription
- Can use hospital's order numbering system
- For distributions to hospital clinics and facilities, if exceed 5%, no drug distributor license required

“Inpatient” vs. “Outpatient”

- Various meanings
- Avoid use of terms
- BOP jurisdiction interpretation:
 - A drug prepared within and administered to a patient within the DHSS licensed hospital premises (regardless of patient billing status):
DHSS jurisdiction

QUESTIONS

Questions-Licensure

What areas are currently included in a DHSS hospital license and how can a hospital determine this?

DHSS Licensed Premises

197.60.2

Each license shall be issued only for the premises and persons or governmental units named in the application, and shall not be transferable or assignable except with written approval of the department of health and senior services....(1953)

DHSS Licensed Premises

197.052

An applicant for or holder of a hospital license may define or revise the premises of a hospital campus to include tracts of property which are adjacent but for a common street or highway, as defined in section 300.010, and its accompanying public right-of-way. (2010)

DHSS Licensed Premises

Rule Revision Draft Language:

Hospital definition:

(A) 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;
- (3) 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;

(B) The term "hospital" does not include convalescent, nursing, shelter or boarding homes as defined in chapter 198, RSMo.

DHSS Licensed Premises

Rule Revision Draft Language:

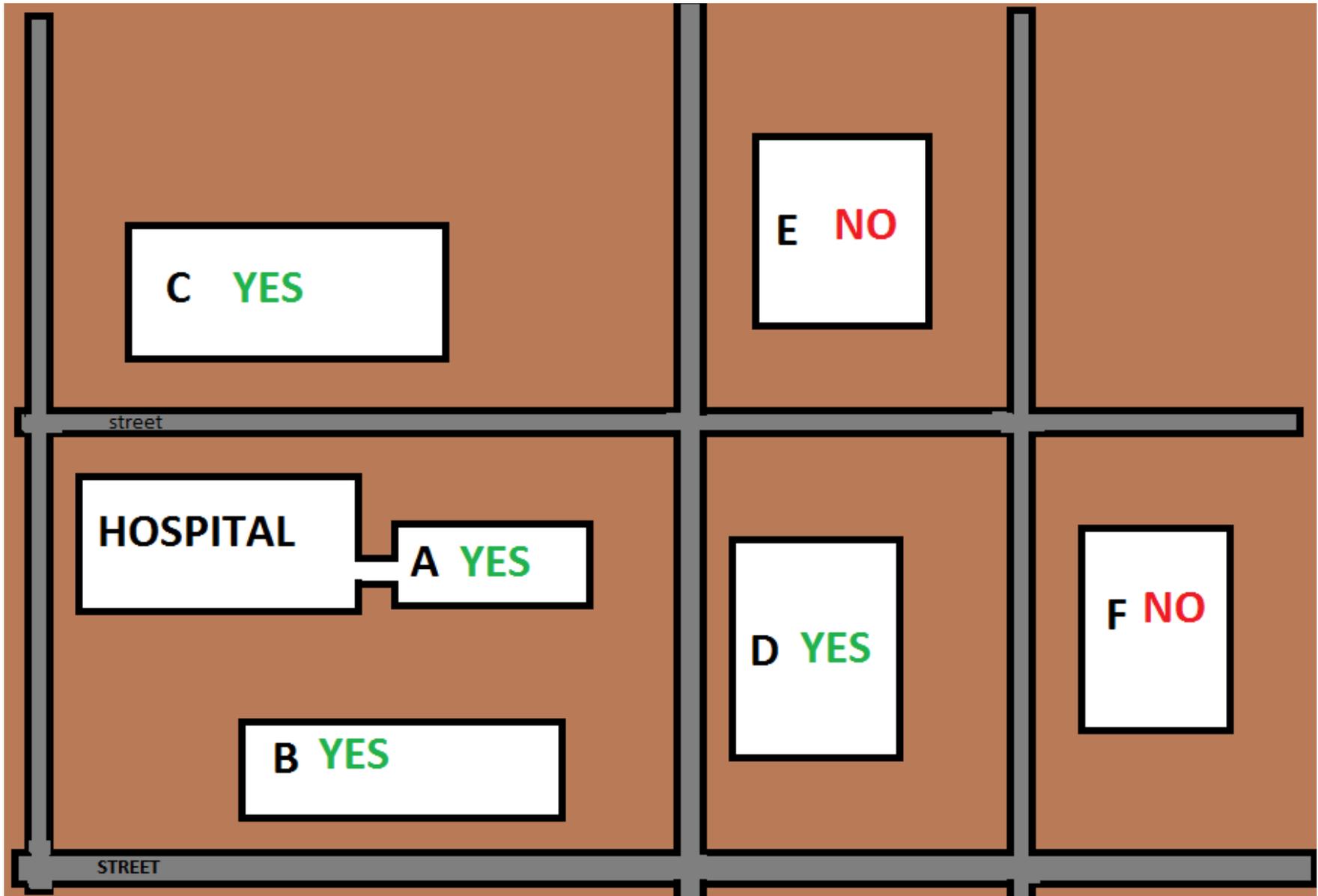
Hospital premises:

- (1) Buildings located on tracts of property which are adjacent to the hospital but for a common street or highway and its accompanying right-of-way may be included in the hospital's license if they meet subsection (A)(1) - (2) above.

DHSS Licensed Premises

- Premises ≠ Hospital campus
- Premises ≠ Hospital system
- Premises ≠ Corporate structure
- Premises ≠ CMS Certification Number (CCN)
- Premises ≠ Patient billing status
- Premises ≠ Provider employment status
- Premises ≠ Other DHSS license (ASC, LTCF)
- Premises ≠ Space rented to other entity

Possible License Scenarios



Questions-Licensure

How can a hospital determine if a clinic, infusion center or other non-inpatient area qualifies for a Class B license?

Statutory Definition

- 338.165

"Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system

- Seek legal guidance in determination, especially for joint ownership or private entity lease

Questions-Licensure

What defines the Class B “licensed area” in a hospital pharmacy, and can a hospital include more than one “area” in a Class B license?

Questions-Licensure

Are there any restrictions on mixed inpatient/outpatient activities or use of common stock for inpatient/outpatient orders/prescriptions in a Class B inpatient pharmacy?

Questions-Licensure

What defines the Class B licensed area in a clinic, and are there restrictions on access by other licensed practitioners?

Questions-MTS

Is a MTS certificate required for a pharmacist to perform routine inpatient “medication order management” procedures?

Statutory Requirement

338.165

4. All pharmacists providing medication therapy services shall obtain a certificate of medication therapeutic plan authority as provided by rule of the board.

Questions-MTS

Can non-employee pharmacists be authorized for hospital MTS protocols, e.g. pharmacists providing remote pharmacy order review and other clinical pharmacy services, including out-of-state pharmacists?

Remote Order Verification

- Pharmacist located in Missouri
 - Hold MO pharmacist license
 - If working outside of pharmacy or hospital, must comply with 20 CSR 2220-2.6055 *Non-Dispensing Activities*
- Pharmacist located outside of Missouri
 - Pharmacist must hold MO pharmacist license, or
 - Must be working in pharmacy holding MO non-resident permit
- Class J is not required on the pharmacy permit
- Remote supervision of technicians is not allowed

Questions-MTS

When is credentialing and privileging required for MTS protocols?

Questions-MTS

Can the same MTS protocols be used for both inpatients and outpatients?

BOP MTS Regulation

20 CSR 2220-6.060; 6.070; 6.080

Requirements

- General
- Physician
- Protocol
- Drug modification
- Recordkeeping

Questions-Drug Distribution

Can a hospital that has a Class B license distribute freely between all facilities within the health system?

Questions-Drug Distribution

Can a hospital that does not have a Class B license or drug distributor license distribute to a hospital-owned clinic or fill medication orders for another hospital owned by the same health system?

Questions-Rules

What will be the process for developing and promulgating the new joint rules?

Questions-Rules

When will the Joint Rule Making Committee be appointed?

Questions-Rules

When will the proposed DHSS hospital pharmacy services rules be sent to the Secretary of State for publication as proposed rules?

**QUESTIONS
FROM PARTICIPANTS**

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

March 2, 2016

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

Committee Members Present

Bert McClary, R.Ph., Chairman
James Gray, R.Ph., Member
Colby Grove, R.Ph., Member
Kevin Kinkade, R.Ph., Member
Neil Schmidt, R.Ph., Member
Greg Teale, R.Ph., Member

Committee Members Absent

Daniel Good, R.Ph.

Staff Present

Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector

Others Present

Christian Tadrus, R.Ph., Board Member
Sarah Wilson, Missouri Hospital Association
Julie Creach, Missouri DHSS

Chairman McClary opened the meeting at 12:01 p.m. and roll-call was taken of meeting attendees. Mr. McClary indicated the administration by prescription order rule and the DHSS hospital related pharmacy rules/proposed rules would be the main agenda items. Greg Teale indicated he's established a google survey to allow members to submit questions for the SB 808 webinar and asked if the link should be sent to other groups. Neil Schmidt indicated he intended to circulate the SB 808 list to MSHP members after the questions have been selected.

Agenda Item # 1: Mr. McClary asked for updates on the proposed DHSS rule. Kimberly Grinston reported the Board previously reviewed the suggestions and did not make any additional changes.

Agenda Item # 2: Bert McClary asked for additional changes/suggestions to the administration by prescription order rule. Committee discussion was held. Substantive

rule changes/suggestions are incorporated in Attachment A. Additionally, the following discussion was held:

- Greg Teale asked if the required administration training programs actually exist and asked if this should be handled in the same manner as competency assessment. Alternatively, Mr. Teale asked if this issue was already addressed in proposed section (10). Bert McClary indicated the rule is applicable to all pharmacists which may require the duplicate language but noted that the current rule or proposed changes do not address a licensed pharmacy within a health care entity. Sarah Wilson also questioned the availability of training programs and asked if additional training was necessary outside of what may have been learned in pharmacy school. Ms. Wilson also noted that hospitals may provide orientation programs but may not provide full training programs in administration technique and practices. Bert McClary indicated older pharmacy school graduates may not have received training in drug administration and questioned if this was covered in current pharmacy school curriculums. Neil Schmidt indicated recent PharmD. graduates may have received administration training. Mr. McClary suggested hospital training should be acceptable.

Sarah Wilson suggested that the rule focus should be on safe administration practices and commented that all pharmacists should be held to the same level of administration training and competency assessment. Kimberly Grinston asked if the rule should address training or competency assessment and indicated these are different activities. Committee members inquired about training requirements for other unlicensed medical assistants such as nursing assistants or LPNs or certified medication technicians. Sarah Wilson indicated that the Board of Healing Arts may allow physicians in private office practices to designate administration activities to unlicensed staff if properly trained. Bert McClary again commented that the original rule intent was to set a practice standard for all pharmacists administering medication.

Mr. Teale cautioned against establishing standards for a Class B hospital and different standards for hospital functions under the jurisdiction of DHSS. Sarah Wilson agreed and indicated this would be a problem for numerous hospitals. James Gray agreed and asked if the proposed rule could require a single standard for hospitals and related hospital administrations. Bert McClary suggested that Committee members bring suggestions for addressing the training and Class B issues to a future meeting.

- Bert McClary questioned if hospitals would have a specific policy just for pharmacist administration and asked if hospitals should be exempt from the policy and procedure section. Greg Teale suggested hospitals would likely have administration criteria that would be applicable to pharmacists based on their role. Julie Creach indicated she would check DHSS rule requirements. Greg Teale suggested striking the policy & procedure requirements for hospitals pending DHSS' answer. However, Neil Schmidt commented some hospital policies may not include pharmacy and suggested it might be beneficial for hospitals to develop policies that are pharmacy/pharmacist specific.

Agenda Item # 3: Bert McClary introduced the topic and indicated his intent was to make the Committee aware of other DHSS rules that may affect hospital pharmacy practice. Kimberly Grinston asked if technicians would fall under the UAP rule. Bert McClary indicated he could not provide a definitive answer but suggested that technicians could likely fall under both the UAP and pharmacy technician definitions depending on their duties. Due to time constraints on the call, Bert McClary suggested revisiting the DHSS rules at a future meeting.

Agenda Item # 7 & # 8: Neil Schmidt suggested that the Committee meet every other month in-person and via conference call during the interim month. Committee consensus to meet as suggested for now. Bert McClary requested that the Committee discuss future meeting formats at a later meeting. The Committee agreed to meet in Jefferson City on April 11, 2016.

ADJOURNMENT

Bert McClary adjourned the meeting by consensus at approximately 2:04 p.m.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:

**Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care
Standards**

20 CSR 2220-6.040 Administration by Medical Prescription Order

PURPOSE: This rule establishes procedures for pharmacists to administer drugs and devices, including ~~devices~~ vaccines, pursuant to medical prescription orders.

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices, including vaccines, pursuant to a medical prescription order.

(2) Definitions. The following definitions shall apply for purposes of this rule:

(1) “Health Care Entity”- A health care entity shall include any entity or organization, other than a pharmacy licensed under Chapter 338, RSMo, that is licensed or certified by the state or federal government to provide health care services and that is required to maintain patient medical records by state or federal law.

(2) “Medical Prescription Order”- A lawful order for drugs or devices issued by an authorized practitioner within the scope of his/her professional practice which is to be dispensed or administered to the ultimate user or recipient.

~~(2)~~(3) The pharmacist may not delegate the administration to another person, except to an ~~pharmacist intern~~ intern pharmacist who has met the qualifications under subsections ~~(3)(B), (C), and (E)~~ (4)(B) - (D) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order. The pharmacist and pharmacist intern shall maintain proof of the intern’s compliance with this subsection.

~~(3)~~(4) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the state Board of Pharmacy. To file a Notification of Intent, a pharmacist must—

(A) Hold a current, ~~unrestricted~~ license to practice pharmacy in this state;

(B) Hold a current ~~provider-level cardiopulmonary resuscitation (CPR)~~ Basic Life Support certification (BLS) issued by the American Heart Association, ~~or~~ the American Red Cross or an equivalent organization. The certificate program must include a live training component;

(C) Successfully complete a certificate program in the administration of drugs ~~accredited provided by: the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy~~ (1) a continuing education provider accredited by the Accreditation Council for Pharmacy Education (ACPE) or (2) a governmental entity, healthcare professional organization or educational institution approved by the Board. To obtain Board approval, the training program must [be taught by qualified instructors/a licensed healthcare professional and] provide instruction in: ~~.-The certificate program must cover a~~

1. Physiology and techniques for routes of administration which must include hands-on training in all routes of administration the pharmacist utilizes;
2. Drug storage and handling;
3. Informed consent requirements, if applicable;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal; and
6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks; and

~~(D) Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;~~

~~(E) Maintain documentation of the above requirements; and.~~

~~(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.~~ (E) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist shall [first] be trained in the techniques of that route of administration by a health care practitioner who is proficient in that

route of administration. The pharmacist shall provide the Board with a written statement from the health care practitioner attesting that both the health care practitioner and the pharmacist are proficient in that route of administration.

~~(4)~~ (5) General Requirements.

(A) A pharmacist shall administer ~~drugs~~ vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC) ~~or in accordance with manufacturer's guidelines.~~ In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs by medical prescription order, ~~including the disposal of used and contaminated supplies and appropriate handling of acute adverse events.~~ The manual Policies and procedures shall be reviewed annually by the pharmacist-in-charge or, for a licensed pharmacy in a health care entity, policies and procedures may be alternatively reviewed by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the health care entity responsible for reviewing clinical practices. Policies and procedures must be available for inspection by the State Board of Pharmacy or other authorized Board representative. Documentation of the annual review must be maintained in the pharmacy's records. At a minimum, the required policies and procedures must include provisions governing:

1. Drug administration procedures, including, authorized routes of administration,
2. Drug storage;
3. Pre- and post- administration assessment and counseling, including, providing vaccine information statements when applicable;
4. Biohazard waste disposal and disposal of used/contaminated supplies;
5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.

(D) Drugs must be stored within the manufacturer's labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.

(E) Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

(F) For pharmacists administering drugs in a health care entity, the policy and procedure review required by this subsection may be performed by the pharmacist-in-charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the health care entity responsible for reviewing clinical practices.

~~(5)~~ (6) Requirements of Medical Prescription Order. The medical prescription order from a ~~licensed prescriber~~ an authorized practitioner must contain at a minimum the following:

(A) The name of the ~~licensed prescriber~~ authorized practitioner issuing the order;

(B) The name of the patient to receive the drug;

(C) The name of the drug and dose to be administered;

(D) The route of administration;

(E) The date of the original order; and

(F) The date or schedule, if any, of each subsequent administration; ~~and~~

~~(G) A statement that the drug is to be administered by a pharmacist.~~

~~(6)~~ (7) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy. For drugs administered by a pharmacist for or on behalf of a health care entity, the information required herein may be recorded in a patient medical record that the health care entity is required to maintain under state or federal law.

1. The name, address, and date of birth of the patient;

2. The date, route, and anatomic site of the administration;

3. The name, dose, manufacturer, ~~lot number~~, and expiration date of the drug. The lot number shall be documented and recorded for vaccines and biologics;

4. For vaccines, the name and address of the patient's primary health care provider, as identified by the patient. The pharmacist shall document in the patient's immunization record if a patient's primary health care provider is unknown or not designated by the patient;

5. The ~~name or identifiable initials~~ identity of the administering pharmacist. If administered by an intern pharmacist, the identity of the intern and the supervising pharmacist; ~~and~~

6. The nature of an adverse reaction and who was notified, if applicable;

7. A patient's refusal or failure to remain in or return to the pharmacy as requested after vaccine administration to observe any adverse reactions; and

8. Written or electronic documentation that required notifications have been sent.

(B) All records required by this regulation shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. Records required by this section may be securely stored offsite at a location designated by the health-care entity, provided records must be produced as provided in section (11) of this rule.

~~(7)~~ (8) Notification Requirements.

(A) A pharmacist administering ~~drugs~~ a vaccine pursuant to a medical prescription order shall notify the ~~prescriber within seventy-two (72) hours~~ patient's primary health care provider, if provided by the patient, within fourteen (14) days after administration of the following:

1. The identity of the patient;
2. The identity of the ~~drug~~ vaccine administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) In the event of any adverse event or reaction experienced by the patient following administration of a drug, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. The prescriber may not opt out of adverse notification requirements.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

(D) Documentation that the required notifications have been sent must be kept at the pharmacy or other authorized location where the prescription order is maintained.

(9) Notification of Intent Refiling. A Notification of Intent to administer drugs by medical prescription order shall be refiled with the state board of pharmacy biennially along with the pharmacist's Missouri pharmacist license. To refile, a pharmacist must:

(A) Hold a current Basic Life Support certification issued by the American Heart Association or the American Red Cross or an equivalent organization. The certification program must include a live training component; and

(B) Have successfully completed four (4) hours of continuing education (0.4 CEU) related to drugs administration. The required continuing education (CE) shall be governed by the rules of the state Board of Pharmacy governing pharmacist CE and may be used to satisfy the pharmacist's biennial pharmacist renewal CE requirements. The initial training program required by subsection (4) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within twelve (12) months prior to refiling the pharmacist's Notification of Intent.

(10) Administration in a Health Care Entity- Pharmacists administering drugs in a health care entity shall comply with the requirements of this rule with the following exceptions:

(A) A pharmacist shall be deemed in compliance with the requirements of sections (5), (6), (7) and (8) of this rule if the pharmacist administers drugs for or on behalf of a health care entity and the administration is lawfully recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law.

(B) In lieu of completing a certificate program in the administration of drugs as required by section (4) of this rule, pharmacists administering in a health care entity shall be trained in administration and meet all competency, training and evaluation requirements required by the health care entity and the Missouri Department of Health and Senior Services (DHSS).

(C) If a pharmacist administering drugs in a health care entity wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist shall [first] be trained in the techniques of that route of administration by a health care practitioner who is proficient in that route of administration. The pharmacist shall provide the

Board with a written statement from the health care practitioner attesting that both the health care practitioner and the pharmacist are proficient in that route of administration.

(D) A pharmacist shall administer vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC).

(E) The policy and procedure review required by section (5) shall be performed by the pharmacist-in-charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the health care entity responsible for reviewing clinical practices.

(F) The records required by this rule may be securely stored offsite at a location designated by the health-care entity, provided records must be produced as provided in section (11) of this rule.

(11) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation as requested by the Board or the Board's authorized designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Board and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and section 338.010.1, RSMo Supp. 2007. Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

**Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
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Division 2220—State Board of Pharmacy
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5. Biohazard waste disposal; and
6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks; and

~~(D) Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;~~

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~~(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.~~ (E) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist shall [first] be trained in the techniques of that route of administration by a health care practitioner who is proficient in that

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1. Drug administration procedures, including, authorized routes of administration,
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5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.

(D) Drugs must be stored within the manufacturer's labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.

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3. The name, dose, manufacturer, ~~lot number~~, and expiration date of the drug. The lot number shall be documented and recorded for vaccines and biologics;

4. For vaccines, the name and address of the patient's primary health care provider, as identified by the patient. The pharmacist shall document in the patient's immunization record if a patient's primary health care provider is unknown or not designated by the patient;

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6. The nature of an adverse reaction and who was notified, if applicable;

7. A patient's refusal or failure to remain in or return to the pharmacy as requested after vaccine administration to observe any adverse reactions; and

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(B) All records required by this regulation shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. Records required by this section may be securely stored offsite at a location designated by the health-care entity, provided records must be produced as provided in section (11) of this rule.

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4. The anatomic site of the administration;
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(B) In the event of any adverse event or reaction experienced by the patient following administration of a drug, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. The prescriber may not opt out of adverse notification requirements.

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(A) A pharmacist shall be deemed in compliance with the requirements of sections (5), (6), (7) and (8) of this rule if the pharmacist administers drugs for or on behalf of a health care entity and the administration is lawfully recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law.

(B) In lieu of completing a certificate program in the administration of drugs as required by section (4) of this rule, pharmacists administering in a health care entity shall be trained in administration and meet all competency, training and evaluation requirements required by the health care entity and the Missouri Department of Health and Senior Services (DHSS).

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**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

DRAFT

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

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.**

Sharon & Brett — can't find this in any regs... any idea where/why we defined it?

(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.**

[An individual who is currently licensed as an anesthesiologist assistant in the state of Missouri].

Why did we go into so much detail here? Why not keep it consistent like the rest of the professions we defined?

(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.**

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(7) [(5)] 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.]

[(6) 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.]

(8) 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.

(9) [(7)] 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.

(10) **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.**

| (110) [(9)] 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** [Council on Certification of Nurse Anesthetists] **and is currently licensed to practice professional nursing in Missouri.**

| Why not keep consistent with the rest of defined Professions? "A person who is currently certified as a Certified Registered Nurse Anesthetist in the State of Missouri."

| (121) [(10)] 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.

| (132) [(11)] 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.

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[(12) 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.]

[(13) 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.]

(14) Credible Allegation – A written or verbal claim or assertion that someone has done something illegal or wrong and is believed to be true.

~~(15)~~ **(16)** 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.]*

~~[(14)/16]~~ **(16)** Dentist—An individual who *[has received a Doctor of Dental Surgery or Doctor of Dental Medicine degree and]* is currently licensed to practice dentistry in **the State of Missouri**.

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~~[(15)/17]~~ **(17)** Department—Missouri Department of Health and Senior Services.

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~~(186)~~ **(186)** ~~[(28) Qualified]~~ Dietitian—An individual who is **currently licensed 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)~~ **(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.~~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~~

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~~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)~~

(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.
- (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.

(2320) [(16)] 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.]*

(241) [(43)] Immediate and serious threat—Having caused, or is likely to cause, serious injury, harm, impairment, or death to a patient.

[(17) 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.]

(252) Licensed practitioner: Any individual who is licensed and qualified to practice a health care profession.

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- | **(263)** [(18)] 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.
- | **(274)** [(19)] 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.**

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- | **(3027)** 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.
- | **(31)** *[Qualified]* 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.
- | **(3228)** 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 *[or a residential care unit]*.
- [(21) 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.]*
- | **(3329)** 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.
- | **(340)** 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.
- | **(354)** 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.
- | **(36)** 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>.
- | **(37)** Observation – the act of paying close attention to someone or something in order to obtain information.

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(328) [(31) *Qualified*] Occupational therapist—An individual who is [a] **currently licensed** [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.]

(33) [(22)39] 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) Ultimate responsibility for making and implementing decisions regarding the operation of the hospital; and

(B) Ultimate financial control of the operation of the hospital.] **Any management consultant or contracted entity who exercises control over the operation of the facility on a day to day basis.**

(40) 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.

(41) [(23)] PALS—The American Heart Association’s pediatric advanced life support program. PALS may be used interchangeably with APLS where required.

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

(43) [(24)] Pharmacist—An individual who is [a graduate of a school or college of pharmacy and is] currently licensed to practice pharmacy in **the State of Missouri.**

(44) Pharmacist Intern – an individual who is currently licensed as a pharmacist intern in the State of Missouri.

(45) Pharmacy technician—an individual who is currently registered as a pharmacy technician in the State of Missouri.

(46) [(32) *Qualified*] Physical therapist—An individual who is **currently** licensed 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 to practice medicine in Missouri.

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

(40) 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.

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(49) Premises – Buildings, floors and areas located on tracts of property which are adjacent to the hospital but for a common street or highway and its accompanying right-of-way may be included in the hospital's license if they meet subsection... **(ADD SUBSECTION)**.

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(50) [(27)] Psychologist—An individual who is currently licensed 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 [t]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 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 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.**

(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.~~

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(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) hours a day care by licensed nursing personnel.~~

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(58) [(34) *Qualified*] **Social worker**—An individual who is licensed 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*].

(59) [(39)] **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.

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

(62) [(41)] **Unit**—A functional division or facility of the hospital.

(63) **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.

*AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154 and 197.293, RSMo Supp. 2005. * This rule was previously filed as 13 CSR 50-20.011. Original rule filed June 2, 1982, effective Nov. 11, 1982. Amended: Filed June 2, 1987, effective Sept. 11, 1987. Amended: Filed Aug. 16, 1988, effective Dec. 29, 1988. Amended: Filed Nov. 21, 1995, effective July 30, 1996. Amended: Filed Oct. 6, 1998, effective April 30, 1999. Amended: Filed June 28, 2001, effective Feb. 28, 2002. Amended: Filed Sept. 20, 2005, effective April 30, 2006.*

**Original authority: 192.006, RSMo 1993; amended 1995; 197.080, RSMo 1953, amended 1993, 1995; 197.154, RSMo 2004; and 197.293, RSMo 2000, 2004.*

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

PROPOSED RULE

19 CSR 30-20.030 Construction Standards

PURPOSE: This rule establishes up-to-date construction standards for hospitals both new and renovated to help ensure accessible, functional, fire-safe and sanitary facilities.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Hospital General Requirements.

(A) A new hospital is one for which plans are submitted to the Department of Health and Senior Services for review and approval on or after the effective date of this rule for the construction of a new facility. Existing hospitals shall continue to meet the construction standards in effect at the time of plan approval. The rule also applies to expansion or renovation projects of existing hospitals or the conversion of an existing facility not previously and continuously licensed as a hospital under Chapter 197, RSMo. A hospital shall be designed to provide all of the facilities required by this rule and arranged to accommodate all of the functions required by this rule and to provide comfortable, sanitary, fire-safe, secure and durable facilities for the patients. In major alteration projects and additions to an existing licensed hospital, only that part of the total hospital affected by the project is subject to this rule. Any change to any building on the hospital premises that alters the structural design, the building type, or expands the patient care services in any building shall first be reviewed and approved by the department prior to implementation of the changes.

(B) These minimum requirements are not intended in any way to restrict innovations and improvements in design, construction or operating techniques. Plans and specifications and operational procedures which contain variances from these requirements may be approved if it is determined that the purposes of the minimum requirements have been fulfilled. Some facilities may be subject to the requirements of more than one (1) regulating agency. While every effort has been made to ensure coordination, facilities making requests for changes in services and request for new construction or renovations are cautioned to verify requirements of other agencies involved.

(C) Requests for variances from the requirements of this rule shall be in writing to the Department of Health and Senior Services. Approvals for variances shall be in writing and both requests and approvals shall become a part of the permanent Department of Health and Senior Services records for the facility.

(D) Alterations or additions to existing hospitals shall be programmed so construction will minimize disruptions of existing functions. Access to exits, fire protections and additionally approved alternative safety measures shall be maintained so the safety of the occupants will not be jeopardized during construction.

(E) The owner of each new facility or the owner of an existing facility being added to or undergoing major alterations shall provide a program---scope of services---which describes space requirements, staffing patterns, departmental relationships and other basic information relating to the objectives of the facility. The program may be general but it shall include a description of each function to be performed, approximate space needed for these functions and the interrelationship of various functions and spaces. The program also shall describe how essential services can be expanded in the future as the demand increases. Appropriate modifications or deletions in space requirements may be made when services are shared or purchased, provided the program indicates where the services are available and how they are to be provided.

(2) Planning and Construction Procedure.

(A) Plans and specifications shall be prepared for the construction of all new hospitals and additions to and major remodeling of existing hospitals. The plans and specifications shall be prepared by an architect or a professional engineer licensed to practice in Missouri.

(B) Construction shall be in conformance with plans and specifications approved by the Department of Health and Senior Services. The Department of Health and Senior Services shall be notified within five (5) days after construction begins. If construction of the project is not started within one (1) year after the date of approval of the plans and specifications, the plans and specifications shall be resubmitted to the Department of Health and Senior Services for its approval and shall be amended, if necessary, to comply with the then current rules before construction work commences.

(3) General Design. Construction shall meet the Guidelines for Design and Construction of Health Care Facilities, Facility Guidelines Institute (FGI), 2010 Edition, except that all references to National Fire Protection Association (NFPA) included in the FGI shall refer to the NFPA 101, 2000 Edition. National Fire Protection Association (NFPA) 101 Life Safety Code, 2000 Edition, and all referenced NFPA publications shall apply to general design and construction. The Guidelines for Design and Construction of Health Care Facilities, Facility Guidelines Institute (FGI), 2010 Edition, are incorporated by reference in this rule and available from the American Society for Healthcare Engineering of the American Hospital Association (ASHE), 155 North Wacker Drive, Chicago, IL 60606, 800-242-2626, www.fgiguideines.org. This rule does not incorporate any subsequent amendments or additions. The National Fire Protection Association (NFPA) 101 Life Safety Code, 2000 Edition, is incorporated by reference in this rule and is available at, 1 Batterymarch Park, Quincy, MA 02269, 617-770-3000, www.nfpa.org. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: section 197.080, RSMo Supp. 2015.

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

PRIVATE COST: This proposed rule 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 rule 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.*

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

PROPOSED AMENDMENT

19 CSR 30-20.086 Medical Staff [in *Hospitals*]. The department is amending the title of the rule and sections (2) through (11), (13), and (14); and adding a new section (15).

PURPOSE: This amendment provides clarification on certain aspects related to medical staff within hospitals and adds a specific comment concerning the appointment of non-physician practitioners to the medical staff.

(2) Medical staff membership shall be limited to physicians, dentists, psychologists and podiatrists. **Non-physician practitioners may be appointed to medical staff if such practice is consistent with the scope of their professional license.** 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 podiatry schooling, postgraduate training or certification. [*if the schooling*] **The school** or postgraduate training **program** for a physician [*was*] **shall be** accredited by the American Medical Association or the American Osteopathic Association[*;*]; for a dentist, [*was*] **shall be** accredited by the American Dental Association[*'s Commission on Dental Accreditation,*]; for a psychologist, [*was*] **shall be** accredited [*with accordance to Chapter 337, RSMo*] **by the American Psychological Association;** and for a podiatrist, [*was*] **shall be** accredited by the American Podiatric Medical Association. Each application for staff membership shall be considered on an individual basis with objective criteria applied [*equally*] **uniformly** to each applicant.

(4) [*Each physician, dentist, psychologist or podiatrist*] **Applicants** requesting staff membership shall submit a complete written **and signed** 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, **a signed statement that they will observe hospital policies and procedures,** and other information **as** required by the medical staff bylaws or policies.

(5) Written criteria shall be developed for privileges extended to each member of the staff. A formal [*mechanism*] **process** 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*] **process** 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 who is denied membership or whose completed application is not acted upon in ninety (90) calendar days [*of*] **from the** completion of **credentialing** verification [*of credentials data*] or a medical staff member 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*] **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.

(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; **standing committees**; committee functions; **frequency of meetings**; 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*] **related to** 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*] **process** shall be established for [*monthly*] **interim** 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 **shall** determine retention guidelines and guidelines for release of minutes not containing peer review materials **in accordance with the hospital records retention policy**.

(13) The medical staff shall establish in its bylaws or rules criteria for the content of [*patients'*] **medical** records, provisions for their timely completion and disciplinary action for noncompliance, **consistent with applicable state and federal law**.

(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 **for emergency care** within a reasonable period of time [*for emergency service*] **that is appropriate to the patient's condition.**

(15) With approval of the governing body, the medical staff may rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site entity physicians and practitioners providing telemedicine services, if the hospital's governing body ensures, through its written agreement with the distant-site entity, that all of the following provisions are met:

(A) The distant-site entity providing the telemedicine services is a Medicare-participating hospital.

(B) The individual distant-site entity physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site entity physician's or practitioner's privileges at the distant-site hospital.

(C) The individual distant-site entity physician or practitioner holds a license issued or recognized by the State of Missouri.

(D) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site entity physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site entity physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site entity physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site entity physician or practitioner.

*AUTHORITY: sections [192.006 and] 197.080[, RSMo 2000] and 197.154, RSMo Supp. [2007] 2015. * This rule previously filed as 19 CSR 30-20.021(2)(C). Original rule filed June 27, 2007, effective Feb. 29, 2008. *Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed amendment with the Missouri Department of Health and Senior Services, Division of Regulation and Licensure, Jeanne Serra, Division Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be

*received within thirty (30) days after publication of this notice in the **Missouri Register**.
No public hearing is scheduled.*

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

PROPOSED AMENDMENT

19 CSR 30 – 20.092 Emergency Services. The department is amending the title of the rule and sections (1), (3), (11) and (12).

PURPOSE: This amendment specifies the requirements for emergency services in all hospital settings and emphasizes the need for proper assessment, treatment or transfer of patients. Clarifying language is also added related to the concept of diversion.

(1) [Each] **Unless it qualifies as a hospital primarily providing [general] psychiatric services [to the community], rehabilitation services, or long term care services, each hospital shall [provide an easily accessible] have a fully equipped emergency [area] service** which shall be [equipped and] staffed to ensure that ill or injured persons can be promptly assessed and treated or transferred to a facility capable of providing needed specialized services. In multiple-hospital communities where written agreements have been developed among the hospitals in accordance with an established community-based hospital emergency plan, individual hospitals may not be required by the Department of Health and Senior Services to provide a fully equipped emergency service. **Individual hospitals including, but not limited to, hospitals primarily providing psychiatric services, rehabilitation services, or long term care services are required to provide an emergency service area and have the same obligation to provide assessment, treatment or transfer, despite the hospital's specialty status.**

(3) Hospital emergency services shall be under the medical direction of a qualified [staff] physician who is board-certified [or board-admissible] in emergency medicine and maintains a knowledge of current ACLS and ATLS standards or a physician who is experienced in the care of critically ill and injured patients and maintains current verification in ACLS and ATLS. In pediatric hospitals, PALS shall be substituted for ACLS. With the explicit advanced approval of the Department of Health and Senior Services, a hospital may contract with a qualified consultant physician to meet this requirement.

(A) That physician shall be responsible for implementing rules of the medical staff relating to patient safety and privileges and to the quality and scope of emergency services.

(B) A qualified registered nurse shall supervise and evaluate the nursing and patient care provided in the emergency area by nursing and ancillary personnel. Supervision may be by direct observation of staff or, at a minimum, the nurse shall be immediately available in the institution.

[(C) Any person assigned to the emergency services department administering medications shall be a licensed physician, registered nurse, EMT-paramedic or appropriately licensed or certified allied health practitioner and shall administer medications only within his/her scope of practice except for students who are participating in a training program to become physicians, nurses, emergency medical technician-paramedics who may be allowed to administer medication under the supervision of their instructors as a part of their training. Trained individuals from the respiratory therapy department may be allowed to administer aerosol medications when a certified respiratory therapy assistant is not available.]

(11) There shall be a [*mechanism*] **process** for the review and evaluation on a regular basis of the quality and appropriateness of emergency services.

(12) A hospital shall have a written plan that details the hospital's criteria and process for diversion. **Diversion 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.** The plan must be reviewed and approved by the Missouri Department of Health and Senior Services prior to being implemented by the hospital. A hospital may continue to operate under a plan in existence prior to the effective date of this section while awaiting approval of its plan by the department.

(A) The diversion plan shall:

1. Identify the individuals by title who are authorized by the hospital to implement the diversion plan;

2. Define the process by which the decision to divert will be made;

3. Specify that the hospital will not implement the diversion plan until the authorized individual has reviewed and documented the hospital's ability to obtain additional staff, open existing beds that may have been closed or take any other actions that might prevent a diversion from occurring;

4. Include that all ambulance services within a defined service area will be notified of the intent to implement the diversion plan upon the actual implementation. Ambulances that have made contact with the hospital before the hospital has declared itself to be on diversion shall not be redirected to other hospitals. In areas served by a real time, electronic reporting system, notification through such system shall meet the requirements of this provision so long as such system is available to all EMS agencies and hospitals in the defined service area;

5. Include procedures for assessment, stabilization and transportation of patients in the event that services, including but not limited to, ICU beds or surgical suites become unavailable or overburdened. These procedures must also include the evaluation of services and resources of the facility that can still be provided to patients even with the implementation of the diversion plan;

6. Include procedures for implementation of a resource diversion in the event that specialized services are overburdened or temporarily unavailable; and

7. Include that all other acute care hospitals within a defined service area will be notified upon the actual implementation of the diversion plan. For defined service areas with more than two (2) hospitals, if more than one-half (1/2) of the hospitals implement their diversion plans, no hospital will be considered on diversion. For a defined service area with two (2) hospitals, if both hospitals implement their diversion plans, neither will be considered on diversion. Participation in a real time, electronic reporting system shall meet the notification requirements of this section. If a hospital participates in an approved community wide plan, the community wide plan may set the requirement for the number of hospitals to remain open.

(B) Each incident of diversion plan implementation must be reviewed by the hospital's existing quality assurance committee. Minutes of these review meetings must be made available to the Missouri Department of Health and Senior Services upon request.

(C) The hospital shall assure compliance with screening, treatment and transfer requirements as required by the Emergency Medical Treatment and Active Labor Act (EMTALA).

(D) A hospital or its designee shall report to the department, by phone or electronically, upon actual implementation of the diversion plan. This implementation report shall contain the time the plan will be implemented. The hospital or its designee shall report to the department, by phone or electronically, within eight (8) hours of the termination of the diversion. This termination report shall contain the time the diversion plan was implemented, the reason for the diversion, the name of the individual who made the determination to implement the diversion plan, the time the diversion status was terminated, and the name of the individual who made the determination to terminate the diversion. In areas served by real time, electronic reporting system, reporting through such system shall meet the requirements of this provision so long as such system generates reports as required by the department.

(E) Each hospital shall implement a triage system within its emergency department. The triage methodology shall continue to apply during periods when the hospital diversion plan is implemented.

(F) Any hospital that has a written approved policy, which states that the hospital will not go on diversion or resource diversion, except as defined in the hospital's disaster plan in the event of a disaster, is exempt from the requirements of [19 CSR 30-20.021(3)(C)12] **this section**.

(G) If a hospital chooses to participate in a community wide plan, the requirements of number of hospitals to remain open, defined service areas, as well as community notification may be addressed within the community plan. Community plans must be approved by the department. Community plans must include that each hospital has a policy addressing diversion and the criteria used by each hospital to determine the necessity of implementing a diversion plan. Participation in a community plan does not exempt a hospital of the requirement to notify the department of a diversion plan implementation.

AUTHORITY: sections [192.006, RSMo, and] 197.080[, RSMo 2000] and 197.154, RSMo Supp. [2007] 2015. This rule previously filed as 19 CSR 30-20.021(3)(C). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

** Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

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

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

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

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

PROPOSED AMENDMENT

19 CSR 30-20.120 Anesthesia Services [in Hospitals]. The department is amending the title of the rule, deleting sections (4) and (8) and renumbering thereafter; and adding new sections (5) through (9); and amending section (3) and the new sections (4), (8), (10) through (12).

PURPOSE: This amendment provides updated language and references for the positions involved in the delivery of anesthesia services in hospitals. Specific additions relate to the evidence of informed consent, the timing and requirements of the medical history and physical examination, and documentation. Post anesthesia requirements previously in a stand-alone regulation have been consolidated into this amendment.

(3) Anesthesia shall be administered only by a **practitioner qualified and authorized under Missouri law to administer anesthesia. This includes** qualified anesthesiologists[,] **and physicians licensed pursuant to Chapter 334, RSMo; [or] dentists [trained in] authorized to administer anesthesia[,]** **under Chapter 332, RSMo; certified registered nurse anesthetists; anesthesiologist assistants; [or] supervised students in [an] approved educational programs; or other practitioners authorized by Missouri law. Anesthesia administered by certified registered nurse anesthetists, anesthesia assistants, or others shall be supervised as required by Missouri laws applicable to their scope of practice.**

(4) *[An anesthesia records documenting the care given shall be a permanent part of the patient's medical record.*

(5) The pre-anesthesia patient evaluation shall be accomplished by **an anesthesiologist, a physician licensed pursuant to Chapter 334, RSMo, or dentist authorized under Chapter 332, RSMo, to administer anesthesia, or certified registered nurse anesthetist under the supervision of an anesthesiologist or other licensed physician, as required by section 334.104, RSMo,** and documented **in the patient's medical record** within forty-eight (48) hours before surgery and shall include the history and physical examination; anesthetic, drug and allergy history; essential laboratory data; and other diagnostic test results to establish potential anesthetic risks. These procedures may be waived in the event of a life threatening emergency provided the surgeon so certifies on the patient medical record.

(5) **Prior to administration of anesthesia, except in the case of emergencies, the patient's medical record shall contain evidence of informed consent.**

(6) **Prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies, a medical history and physical examination shall be completed and**

documented in the patient's medical record no more than thirty (30) days before or twenty-four (24) hours after admission or registration.

(7) Except in the case of emergencies, an updated examination of the patient, including any changes in the patient's condition, shall be completed and documented in the patient's medical record within twenty-four (24) hours after admission or registration when the medical history and physical examination are completed within thirty (30) days before admission or registration.

(8) An anesthesia record documenting the anesthesia care given shall be a permanent part of the patient's medical record. The record shall contain at a minimum the name and hospital identification number of the patient; name of practitioner who administered anesthesia; and as applicable, the name and profession of the supervising anesthesiologist or supervising physician or qualified dentist; name, dosage, route and time of administration of drugs and anesthesia agents; intravenous fluids; any blood or blood products used; oxygen flow rate; continuous recordings of patient status noting blood pressure, heart and respiration rate; and any complications or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment.

(9) Patients receiving post-anesthesia recovery care shall be closely observed by qualified personnel until each patient is stabilized for safe transfer. Written procedures for discharge from the post-anesthesia recovery service shall be approved by the medical staff.

[(6)] (10) A post-anesthesia evaluation shall be completed and documented in the patient's medical record [*within twenty-four (24)*] by qualified anesthesiologists, physicians licensed pursuant to Chapter 334, RSMo, or dentist authorized under Chapter 332, RSMo, to administer anesthesia, or certified registered nurse anesthetist under the supervision of an anesthesiologist or other licensed physician, as required by section 334.104, RSMo, no later than forty-eight (48) hours after surgery or a procedure requiring anesthesia services. The evaluation shall include respiratory function, including respiratory rate, airway patency, and oxygen saturation; cardiovascular function, including pulse rate and blood pressure; mental status; temperature; pain; nausea and vomiting; and postoperative hydration.

[(7)] (11) The use of flammable anesthetic agents shall be limited to those areas of the hospital which comply with all applicable requirements of the [*Standard for Inhalation Anesthetics 1980 published by the National Fire Protection Association*] *NFPA 99, Standard for Health Care Facilities, 1999; and NFPA 101, Life Safety Code, 2000*, which are incorporated by reference in this rule and are published by the National Fire Protection Association (NFPA), NFPA Headquarters, 1 Batterymarch Park, Quincy, MA 02169. This rule does not incorporate any subsequent amendments or additions.

[(8)] *Prior to surgery, the patient's medical record shall contain evidence that the patient has been advised regarding the surgical procedure(s) contemplated, the type of anesthesia to be*

administered and the risks involved with each. Evidence that informed consent has been given shall become a part of the patient's medical record.

(9)] **(12)** There shall be a [*mechanism*] **process** for the review and evaluation on a regular basis of the quality and scope of anesthesia services.

AUTHORITY: sections [192.006 and] 197.080[, RSMo 2000] and 197.154, RSMo Supp. [2007] 2015. This rule previously filed as 19 CSR 30-20.021(4)(B). Original rule filed June 27, 2007, effective Feb. 29, 2008. *Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

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

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

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

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

PROPOSED AMENDMENT

19 CSR 30 – 20.126 Obstetrical and Newborn Services [in Hospitals]. The department is deleting sections (11), (12), (14) and (18); and renumbering thereafter, amending the title of the rule and sections (2) through (5), (7), (8), (10), (12) and (15).

PURPOSE: This proposed amendment updates language throughout, adds a specific policy requirement related to ensuring the safety of mothers and neonates, and identifies the need for a specific policy for the handling of breast milk. Clarifications have been made in regard to patients receiving intravenous oxytocin.

(2) Obstetrical services shall be supervised by a qualified registered professional nurse **leader** with relevant education, experience and demonstrated current competency.

(3) The **nurse leader responsible for** obstetrical nursing [*supervisor*] **services** shall have the authority to implement and enforce hospital policies and procedures governing obstetrical services and shall have the responsibility for evaluating the competency of nursing personnel assigned to obstetrical services.

(4) [*Facilities for obstetrical services shall be designed to*] **The hospital shall have policies, procedures and a process to ensure the safety of the mother and neonate, prevent abduction and** prevent unauthorized traffic.

(5) Undelivered patients receiving intravenous oxytocin shall [*be under continuous observation by trained personnel*] **have one-to-one (1:1) observation by a physician or a registered professional nurse competent in obstetrics.** Induction or augmentation of labor with oxytocin may be initiated only after a qualified physician **or a registered professional nurse in consultation with a qualified physician** has evaluated the patient[.]; determined that induction or augmentation is **indicated and** beneficial to the mother, fetus, or both; recorded the indication and established the plan of management. The physician **or certified nurse midwife** initiating these procedures **or the provider to whom care is transferred** shall be readily accessible to manage complications that arise during infusion [*and a*]. A physician who has privileges to perform Caesarean deliveries shall be in consultation and readily accessible in order to manage any complications that require surgical intervention.

(7) Each newborn **before separation of mother and baby** shall be identified by an acceptable method which includes the name, date and time of birth, the infant's sex and the mother's hospital number.

(8) A [*delivery room*] record **of the delivery** shall be maintained.

(10) Hospitals with an obstetrical service shall have at least one (1) premature-care incubator. *[by an independent testing laboratory]*. **An incubator or bassinet with controlled temperature shall be available for each delivery room.**

(11) *[All cases of acute infectious conjunctivitis (Ophthalmia neonatorum) shall be reported immediately to the individual(s) responsible for the infection control program and in writing to the local or district health department in accordance with section 210.080, RSMo.*

(12) *All cases of epidemic diarrhea of the newborn shall be reported immediately to the individual(s) responsible for the infection control program and the local or district health department.*

13] Resuscitation, suction, oxygen, monitoring and newborn temperature control equipment shall be available for the care of newborn. Supplies for the proper care of newborn shall be available.

[(14) An incubator or bassinet with controlled temperature shall be available for each delivery room and for transport to the nursery.

(15)] **(12)** Space shall be provided for *[the preparation or]* the handling and storage of formula **and breast milk**. Separate refrigeration shall be provided for *[formula]* **breast milk**. **Policies and procedures shall be developed and maintained regarding labeling and handling of breast milk.**

[(16)] (13) Eye care of newborn shall be in accordance with section 210.070, RSMo.

[(17)] (14) Written policies and procedures shall be established to provide safe transport of infants within the hospital or to another health-care facility.

[(18) Written policies and procedures governing special care programs shall be approved by the medical staff and governing body.

(19)] **(15)** There shall be a **process** *[mechanism]* for the review and evaluation on a regular basis of the quality of obstetrical and newborn services provided.

AUTHORITY: sections [192.006 and] 197.080[, RSMo 2000] and 197.154, RSMo Supp. [2007] 2015. This rule previously filed as 19 CSR 30-20.021(4)(E). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

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, 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.*



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

19 CSR 30-20.001 Anesthesiologist Assistants in Hospitals

PURPOSE: This rule allows the use of anesthesiologist assistants in hospitals.

(1) Anesthesiologist assistant—A person who meets each of the following conditions:

(A) Has graduated from an anesthesiologist assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency;

(B) Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;

(C) Has active certification by the National Commission on Certification of Anesthesiologist Assistants;

(D) Is currently licensed as an anesthesiologist assistant in the state of Missouri; and

(E) Provides health care services delegated by a licensed anesthesiologist.

(2) Notwithstanding any other rule in this chapter, anesthesia in hospitals shall be administered only by qualified anesthesiologists, physicians or dentists trained in anesthesia, certified nurse anesthetists, anesthesiologist assistants or supervised students in an approved educational program. Notwithstanding the provisions of sections 334.400 to 334.430, RSMo, or the rules of the Missouri State Board of Registration for the Healing Arts, the governing body of every hospital shall have full authority to limit the functions and activities that an anesthesiologist assistant performs in such hospital. Nothing in this section shall be construed to require any hospital to hire an anesthesiologist who is not already employed as a physician prior to August 28, 2003.

AUTHORITY: sections 192.006 and 197.080, RSMo 2000. Original rule filed Jan. 16, 2007, effective Aug. 30, 2007.*

**Original authority: 192.006, RSMo 1993, amended 1995 and 197.080, RSMo 1953, amended 1993, 1995.*

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) 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.

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

(4) ATLS—The American College of Surgeon's advanced trauma life support program.

(5) Authenticate—To prove authorship, for example, by written signature, identifiable initials or computer key. 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.

(6) 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.

(7) Board-admissible—That a physician 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.

(8) Board-certified—That a physician has fulfilled all requirements, has satisfactorily completed all written and oral examinations and has been awarded a board diploma in a specialty field.

(9) 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 certi-

fication as a nurse anesthetist by the Council on Certification of Nurse Anesthetists.

(10) 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.

(11) 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.

(12) 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.

(13) 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.

(14) Dentist—An individual who has received a Doctor of Dental Surgery or Doctor of Dental Medicine degree and is currently licensed to practice dentistry in Missouri.

(15) Department—Missouri Department of Health and Senior Services.

(16) Hospital emergency transfer policy—A document that represents the usual and customary practices of a hospital with respect to the transfer of patients. The 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.



(17) 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.

(18) 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.

(19) 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;

(C) Cultures and stocks of infectious agents and associated biologicals—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;

(D) Isolation wastes—Wastes generated by hospitalized patients who have communicable diseases capable of being transmitted to others via those wastes;

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

(F) Sharps—All discarded sharps including hypodermic needles, syringes and scalpel blades. Broken glass or other sharp items that have come in contact with material defined as infectious are included.

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

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

(22) 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) Ultimate responsibility for making and implementing decisions regarding the operation of the hospital; and

(B) Ultimate financial control of the operation of the hospital.

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

(24) Pharmacist—An individual who is a graduate of a school or college of pharmacy and is currently licensed to practice pharmacy in Missouri.

(25) Physician—An individual who has received a Doctor of Medicine or Doctor of Osteopathy degree and is currently licensed to practice medicine in Missouri.

(26) Podiatrist—An individual who has received a Doctor of Podiatric Medicine degree and is currently licensed to practice podiatry in Missouri.

(27) Psychologist—An individual who is currently licensed by the State Committee of Psychologists under the provisions of Chapter 337, RSMo.

(28) Qualified dietitian—An individual who is 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.

(29) Qualified medical record administrator—A registered record administrator who has successfully passed an appropriate examination conducted by the American Medical Record Association or who has the document equivalent in education and training.

(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.

(31) Qualified occupational therapist—An individual who is a 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.

(32) Qualified physical therapist—An individual who is licensed to practice professional physical therapy in Missouri.

(33) Qualified radiologic technologist—An individual who is a graduate of a program in radiologic technology approved by the Council on Medical Education of the American Medical Association or who has the documented equivalent in education and training.

(34) Qualified social worker—A licensed clinical social worker or a person who has a bachelor's degree in social work or a master's degree in social work.

(35) Registered nurse—An individual who is a graduate of an approved school of nursing and who is licensed to practice as a registered nurse in Missouri.

(36) Registered or certified respiratory therapist—An individual who has been 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.

(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.

(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.



(39) Special care 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.

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

(41) Unit—A functional division or facility of the hospital.

(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.

(A) 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.

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

AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154 and 197.293, RSMo Supp. 2005. This rule was previously filed as 13 CSR 50-20.011. Original rule filed June 2, 1982, effective Nov. 11, 1982. Amended: Filed June 2, 1987, effective Sept. 11, 1987. Amended: Filed Aug. 16, 1988, effective Dec. 29, 1988. Amended: Filed Nov. 21, 1995, effective July 30, 1996. Amended: Filed Oct. 6, 1998, effective April 30, 1999. Amended: Filed June 28, 2001, effective Feb. 28, 2002. Amended: Filed Sept. 20, 2005, effective April 30, 2006.*

**Original authority: 192.006, RSMo 1993; amended 1995; 197.080, RSMo 1953, amended 1993, 1995; 197.154, RSMo 2004; and 197.293, RSMo 2000, 2004*

19 CSR 30-20.015 Administration of the Hospital Licensing Program

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 a hospital license.

(1) 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(8-01)) included herein. 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. Each application for license to operate a hospital shall be accompanied by the appropriate licensing fee 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 and persons named in the application. 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 one (1) federal tax number; or

(D) The board of directors with management control is an entity other than the licensed operator.

(3) An operator of two (2) or more licensed hospitals may submit application to the Department of Health 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 dis-

tance 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 approves the application, the applicant shall submit an operational proposal to the director of the Department of Health 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 directed by a common medical director and will be subject to the same 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



AUTHORITY: sections 192.006, 197.080, and 197.293, RSMo 2000.* This rule was previously filed as 13 CSR 50-20.015. Original rule filed April 9, 1985, effective July 11, 1985. Amended: Filed Nov. 4, 1992, effective June 7, 1993. Amended: Filed Nov. 21, 1995, effective July 30, 1996. Amended: Filed Oct. 6, 1998, effective April 30, 1999. Amended: Filed June 28, 2001, effective Feb. 28, 2002. Amended: Filed April 30, 2004, effective Dec. 30, 2004.

*Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.293, RSMo 2000.

19 CSR 30-20.021 Organization and Management for Hospitals (Rescinded February 29, 2008)

AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154, RSMo Supp. 2005. This rule was previously filed as 13 CSR 50-20.021 and 19 CSR 10-20.021. Original rule filed June 2, 1982, effective Nov. 11, 1982. Amended: Filed April 9, 1985, effective Sept. 28, 1985. Amended: Filed June 2, 1987, effective Sept. 11, 1987. Amended: Filed Nov. 16, 1987, effective March 26, 1988. Amended: Filed June 14, 1988, effective Oct. 13, 1988. Amended: Filed Aug. 16, 1988, effective Dec. 29, 1988. Amended: Filed Nov. 21, 1995, effective July 30, 1996. Amended: Filed Oct. 6, 1998, effective April 30, 1999. Amended: Filed June 28, 2001, effective Feb. 28, 2002. Amended: Filed April 30, 2004, effective Dec. 30, 2004. Emergency amendment filed Sept. 1, 2005, effective Sept. 11, 2005, expired March 9, 2006. Amended: Filed Feb. 1, 2006, effective July 30, 2006. Rescinded: Filed June 27, 2007, effective Feb. 29, 2008.

19 CSR 30-20.030 Construction Standards for New Hospitals

PURPOSE: This rule establishes up-to-date construction standards for new hospitals to help ensure accessible, functional, fire-safe and sanitary facilities.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or

the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) New Hospital General Requirements.

(A) A new hospital is one for which plans are submitted to the Department of Health for review and approval after November 11, 1982 for the construction of a new facility, expansion or renovation of an existing hospital or the conversion of an existing facility not previously and continuously licensed as a hospital under Chapter 197, RSMo. A new hospital shall be designed to provide all of the facilities required by this rule and arranged to accommodate all of the functions required by this rule and to provide comfortable, sanitary, fire-safe, secure and durable facilities for the patients. In major alteration projects and additions to an existing licensed hospital, only that part of the total hospital affected by the project is subject to this rule.

(B) These minimum requirements are not intended in any way to restrict innovations and improvements in design, construction or operating techniques. Plans and specifications and operational procedures which contain deviations from these requirements may be approved if it is determined that the purposes of the minimum requirements have been fulfilled. Some facilities may be subject to the requirements of more than one (1) regulating agency. While every effort has been made to ensure coordination, facilities making requests for changes in services and request for new construction or renovations are cautioned to verify requirements of other agencies involved.

(C) Requests for deviations from the requirements of this rule shall be in writing to the Department of Health. Approvals for deviations shall be in writing and both requests and approvals shall become a part of the permanent Department of Health records for the facility.

(D) Alterations or additions to existing hospitals shall be programmed so construction will minimize disruptions of existing functions. Access to exits and fire protections shall be maintained so the safety of the occupants will not be jeopardized during construction.

(E) The owner of each new facility or the owner of an existing facility being added to or undergoing major alterations shall provide a program—scope of services—which describes space requirements, staffing patterns, departmental relationships and other basic information relating to the objectives of the facility. The program may be general but it shall include a description of each function to

be performed, approximate space needed for these functions and the interrelationship of various functions and spaces. The program also shall describe how essential services can be expanded in the future as the demand increases. Appropriate modifications or deletions in space requirements may be made when services are shared or purchased, provided the program indicates where the services are available and how they are to be provided.

(2) Planning and Construction Procedure.

(A) Plans and specifications shall be prepared for the construction of all new hospitals and additions to and major remodeling of existing hospitals. The plans and specifications shall be prepared by an architect or a professional engineer licensed to practice in Missouri.

(B) Construction shall be in conformance with plans and specifications approved by the Department of Health. The Department of Health shall be notified within five (5) days after construction begins. If construction of the project is not started within one (1) year after the date of approval of the plans and specifications, the plans and specifications shall be resubmitted to the Department of Health for its approval and shall be amended, if necessary, to comply with the then current rules before construction work commences.

(3) General Design.

(A) Site.

1. The facility shall be located so it is reasonably accessible to the community served, close to where competent medical and professional consultation is readily available and where employees can be recruited and retained.

2. Fire lanes shall be provided and kept clear to provide immediate access for the fire fighting equipment.

3. Paved roads shall be provided within the lot lines to provide access to the main entrance, emergency entrance, entrances serving community activities and to service entrances, including loading and unloading docks for delivery trucks. Hospitals having an organized emergency service shall have the emergency entrance well marked to facilitate entry from the public roads or streets serving the site. Access to the emergency entrance shall not conflict with other vehicular traffic or pedestrian traffic. Paved walkways shall be provided for necessary pedestrian traffic.

4. Documentation of parking needs shall be provided by the hospital as part of the program.

(B) Special Design Considerations for the Handicapped.



1. One-half (1/2) of one percent (1%) of bed capacity or two (2) parking spaces, whichever is greater, shall be provided for handicapped visitors. Parking spaces for handicapped staff members shall be provided as required. Parking spaces for handicapped persons shall be at least twelve feet (12') wide and on level grade. Parking spaces for handicapped shall be located so there is access to sidewalks without going behind other parked cars.

2. Walkways and curbs from the street or parking spaces to the building entrance shall be designed to facilitate travel by people in wheelchairs or on crutches.

3. Parking spaces and one (1) or more entrances to a facility shall be designed to facilitate the building's use by handicapped persons.

4. At least one (1) primary grade-level entrance to the building shall be arranged to be fully accessible to handicapped persons.

5. At least one (1) drinking fountain, one (1) toilet and one (1) hand washing facility shall be available on each floor for physically handicapped patients and staff. At least one (1) wheelchair shower shall be provided in the patient area. Floors where the handicapped are specifically excluded from the entire area, such as boiler rooms, need not meet these requirements.

6. A public telephone, drinking fountain and toilets with hand washing facilities accessible to handicapped visitors shall be located in the hospital.

7. In an alteration project and additions to an existing hospital, only that portion of the total hospital affected by the project, including that part of adjacent areas used for access by the handicapped, must comply with paragraphs (3)(B)1.-6. of this rule.

(4) General Design of Nursing Unit—Adult Medical, Surgical and Post-Partum Care (except special care areas such as recovery rooms, intensive care units and psychiatric units).

(A) Every room shall have direct access to a corridor, shall have a window and shall contain a lavatory, closets and electrical and mechanical facilities. No room shall contain more than four (4) beds. No bed shall have more than one (1) bed between it and the window wall. The room area exclusive of toilet rooms, closets, lockers, wardrobes, alcoves or vestibules shall be not less than one hundred (100) square feet in a single-bed room nor less than eighty (80) square feet for each bed in a multi-bed room. The ceiling shall be not less than eight feet (8') above the floor.

(B) Every bed shall have aisles at least three feet (3') wide on both sides. The aisle between adjacent beds may serve both beds and may serve as access to facilities serving both beds. Each aisle between a bed and wall shall serve as access only to facilities serving the adjacent bed, except the window and the heating unit. An aisle, not less than four feet (4') wide in multi-bed rooms and not less than three feet (3') wide in single-bed rooms, shall be provided at the foot of each bed. Aisles shall be continuous and clear of any built-in equipment with the exception of a heating or air-conditioning unit not more than three feet (3') high and extending not more than nine inches (9") into a side aisle. A unit combining a side table and electrical facilities specially designed for convenience to the patient and for convenient access for patient care may be installed in a side aisle.

(C) Each bed in a multi-bed room shall be provided with cubicle curtains or equivalent facilities arranged to contain adjacent floor space and to provide intermittent visual privacy, but shall not restrict patient access to the lavatory and toilet.

(D) One (1) or more windows, with sash not more than three feet (3') above the floor and with gross area not less than ten percent (10%) of the floor area of the room, shall be provided. If the building has an engineered smoke control system which complies with *Standard for Air Conditioning and Ventilating Systems 1978* published by the National Fire Protection Association, windows are not required to be operable. Otherwise, at least one (1) window or screened vent to the outside in each patient room shall be operable. Operable windows may be operable by a tool located in the nursing unit. Operable windows not restricted to emergency use shall be equipped with screens. Windows shall be exposed to an outside area not less than thirty feet (30') horizontally opposite the window and containing no construction which would further diminish the exposure of the window to natural light.

(E) Access to the corridor shall be either direct or through a vestibule and through one (1) or more doors. A single door leaf may be used if it is at least forty-four inches (44") wide. If double doors are used, both leaves shall equal at least forty-four inches (44") and one (1) leaf shall be at least thirty-two inches (32") wide. Doors shall not swing into the corridor unless recessed to avoid intrusion into the flow of traffic. The door hardware shall permit entry and egress without the use of hands. The toilet door shall swing out except when equipped with emergency rescue hardware.

(F) A toilet is required adjacent to each room with direct access without entering the corridor. It shall contain a water closet with a bedpan cleanser and also may contain a lavatory. It may serve more than one (1) room, but in no case more than four (4) beds. A lavatory equipped with a faucet with goose-neck spout and wrist blades shall be provided in each room. The lavatory shall be accessible without entering a toilet unless the toilet serves only one (1) bed.

(G) A separate closet or built-in wardrobe, suitable for hanging full-length garments on clothes hangers and for storage of personal effects, shall be provided for each bed.

(H) General lighting, switchable at the door, shall be sufficient to provide a light intensity of fifteen (15) foot-candles in all parts of the room. A nonswitchable night light, arranged to avoid shining in the patients' eyes, shall be provided. A reading light, switchable from the bed, shall be provided for each bed. The toilet light shall be switchable at the toilet door. A switchable light shall be provided at each lavatory. All switches for lighting in patient areas shall be of the quiet operating type. Duplex grounding type convenience outlets shall be provided as follows: one (1) on each side of each bed in the headwall for clinical equipment, one (1) at each lavatory and at least one (1) outlet on each wall space in the room. If television and electric beds are installed, grounding type receptacles shall be provided for each.

(I) The nurses' call system shall be installed in accordance with subparagraphs (26)(F)1.A.-F. of this rule.

(J) Oxygen supply outlets and clinical suction outlets shall be accessible from each bed in accordance with paragraph (27)(F)3. of this rule.

(K) At least one (1) room in the hospital shall meet the following isolation requirements:

1. Entrance from the corridor shall be through an anteroom which contains facilities to assist staff in maintaining aseptic conditions. The anteroom shall contain a lavatory or sink equipped for handwashing, storage spaces for clean and soiled materials and gowning facilities;

2. The door to the room shall have a viewing panel for observation from the anteroom; and

3. A private toilet containing a water closet and a tub or shower shall be provided. A handwashing facility shall be located in the toilet or in the patient room.

(L) If suitable psychiatric facilities are not available in the community, at least one (1) room shall be equipped to provide for disturbed patients needing close supervision.



This room shall be designed to minimize the potential for escape, injury or suicide. The door to this room shall swing outward and be recessed so it does not intrude on the flow of traffic.

(5) A service area shall be located in or be readily available to each nursing unit. The location and disposition of each service area will depend upon the number and types of beds to be served. Each service area may be arranged and located to serve more than one (1) nursing unit, but at least one (1) service area shall be provided on each nursing floor. In addition to a nurses' station, nurses' office, equipment storage room, charting facilities and staff toilet facilities, service areas shall include:

(A) Janitors' closet with mop sink, mop rack and space for equipment;

(B) A medicine preparation area containing a work counter with sink, refrigerator and locked storage for biologicals and drugs;

(C) At least one (1) treatment room with handwashing sink for each floor. If all patient rooms are single, this room may be omitted;

(D) A clean workroom or clean holding room. The clean workroom shall contain a work counter and handwashing and storage facilities including cart parking space. The clean holding room shall be part of a system for storage and distribution of clean and sterile supply materials and shall be similar to the clean workroom except that the work counter and handwashing facilities may be omitted;

(E) A soiled workroom or soiled holding room. The soiled workroom shall contain a clinical sink or equivalent flushing rim fixture, work counter with a sink suitable for handwashing, waste receptacle and linen receptacle. A soiled holding room shall be part of a system for collection and disposal of soiled materials and shall be similar to the soiled workroom except that the clinical sink and work counter may be omitted;

(F) Clean linen storage space in a separate closet or as a designated area within the clean workroom or holding room. If a closed cart system is used, storage may be in an alcove;

(G) A nourishment station with a sink, refrigerator, storage cabinets, icemaker, ice dispenser and equipment for serving nourishments between meals;

(H) Space for parking stretchers and wheelchairs located out of the path of normal traffic; and

(I) In nursing units, bathtubs or showers shall be provided at the rate of one (1) for each twelve (12) beds which are not otherwise served by bathing facilities within patients' rooms. Each tub or shower shall be

in an individual room or enclosure which provides space for the private use of the bathing fixture and for drying and dressing. At least one (1) shower on each patient floor shall have space for a wheelchair. At least one (1) shower shall be provided for each twelve (12) beds in post-partum units.

(6) Special Care Units.

(A) Special care patients may be housed in single-bed rooms or in multi-bed rooms. If multi-bed rooms are provided, at least one (1) single-bed room shall be provided for each unit. In any case, one (1) room shall be set up for isolation techniques.

(B) All beds shall be arranged to permit direct visual observation by nursing staff or patient shall be electronically monitored.

(C) Natural lighting by windows shall be available to each patient. One (1) window may serve more than one (1) patient space, but not more than two (2). Window sills shall not be more than three feet (3') above the floor. Unless the building is designed with an engineered smoke control system in accordance with *Standard for Air Conditioning and Ventilating Systems 1978* published by the National Fire Protection Association, at least one (1) window in each room shall be operable. The use of a tool located in the unit is acceptable for window operation.

(D) Clearance between beds in multi-bed rooms shall not be less than six feet (6'). Clearance between the bed and adjacent wall shall not be less than three feet (3') and a clear aisle of at least four feet (4') shall be provided between the foot of the bed and wall. Single-bed rooms or solid wall cubicles shall have a minimum clear area of one hundred twenty (120) square feet and a minimum dimension of ten feet (10').

(E) Viewing panels shall be provided in doors and walls for observation of patients. Glazing in viewing panels shall be nonshattering glass.

(F) A handwashing lavatory shall be provided in each patient's room. In multi-bed rooms, a lavatory is to be provided at a ratio of no less than one (1) lavatory for each six (6) beds.

(G) Each special care unit shall have a toilet facility which is directly accessible from the unit. In multi-bed rooms, toilets are to be provided at a ratio of one (1) toilet for each six (6) beds. Portable water closet units may be used.

(H) Individual lockers shall be provided for the storage of patients' clothing and personal effects. Lockers shall be large enough to permit hanging of full-length garments.

(I) A separate waiting room shall be provided for visitors to special care patients

unless the special care unit is on the same floor as the main waiting room.

(J) A clean workroom with work counter handwashing facility and storage space shall be provided unless an alternate system for storage and distribution of clean and sterile supplies is approved.

(K) A work counter with a sink, waste receptacle and linen receptacle shall be provided unless it can be shown that the soiled holding room is part of a system for collecting soiled materials.

(L) Facilities for flushing and washing bedpans shall be provided within the unit.

(M) A nourishment station with counter, sink, ice dispenser and refrigerator shall be located in or adjacent to the unit.

(N) Storage space for equipment shall be provided. Space shall be provided in the unit for emergency equipment and supplies.

(O) A medicine preparation facility containing a work counter with sink, refrigerator and locked storage for biologicals and drugs shall be provided.

(P) A toilet room equipped with water closet and lavatory shall be provided for staff. A lounge shall be provided for staff. Facilities for safekeeping of coats and personal belongings of personnel shall be provided.

(Q) A janitors' facility shall be located within or adjacent to the special care unit.

(7) Emergency Facilities.

(A) As a minimum, hospitals shall provide the following:

1. A sheltered entrance at grade level accessible to the pedestrian and a sheltered ambulance unloading area;

2. At least one (1) treatment room with handwashing facilities, cabinets, medication storage space, work counter, suction and oxygen outlets, X-ray film illuminator and space for storage of emergency equipment;

3. A patient's toilet convenient to the treatment room; and

4. A janitors' closet.

(B) Hospitals providing a fully equipped emergency service shall have, in addition to paragraphs (7)(A)1., 2. and 4. of this rule, the following:

1. A reception and control area convenient to the emergency entrance, waiting room and treatment rooms;

2. Public waiting space with toilet facilities, public telephone and drinking fountain;

3. Storage space for wheelchairs and stretchers out of line of traffic;

4. Clean supply storage space and clean utility facilities; and

5. Soiled work area containing a clinical sink, work counter with handwashing facility and waste and soiled linen receptacles.



(8) Surgical Facilities.

(A) If surgical facilities are provided, the number of operating rooms, recovery beds and the size of the service areas shall be based on the scope of services to be provided.

(B) The surgical suite shall be located and arranged to preclude unrelated traffic through the suite.

(C) Each general operating room shall have a minimum clear area of three hundred sixty (360) square feet exclusive of fixed and movable cabinets and shelves. The minimum dimension shall be eighteen feet (18'). Ceilings shall be at least nine feet six inches (9'6") high to accommodate surgical lights.

(D) Operating rooms for surgical cystoscopic and other endoscopic procedures shall have a minimum clear area of two hundred fifty (250) square feet exclusive of fixed and movable cabinets and shelves.

(E) A control station located to permit visual surveillance of all traffic which enters the operating suite shall be provided.

(F) An emergency communications system connecting the operating rooms and the surgical suite control station shall be provided.

(G) A high speed autoclave shall be conveniently located to serve all operating rooms.

(H) Space for the storage and preparation of medications shall be provided.

(I) A minimum of one (1) scrub station shall be provided for each operating room.

(J) A soiled workroom for the exclusive use of the surgical suite staff or a soiled holding room, that is part of a system for collection and disposal of soiled material, shall be provided. The soiled workroom shall contain a clinical sink or equivalent flushing-type fixture, work counter with a double sink, sink equipped for handwashing, waste receptacle and linen receptacle. A soiled holding room shall be similar to the soiled workroom except that the work counter may be omitted.

(K) A clean workroom or a clean supply room shall be provided. A clean workroom is required when clean materials are assembled within the surgical suite prior to use. A clean workroom shall contain a work counter, sink equipped for handwashing and space for clean and sterile supplies. A clean supply room shall be provided when the program defines a system for the storage and distribution of clean and sterile supplies which would not require the use of a clean workroom.

(L) A separate room shall be provided for storage of flammable anesthetics unless the use of flammable anesthetics is prohibited in writing by hospital board action.

(M) An anesthesia workroom for cleaning, testing and storing anesthesia equipment shall

be provided. It shall contain a work counter and sink.

(N) Storage space for equipment and supplies shall be provided.

(O) Appropriate areas shall be provided in the surgical suite for male and female personnel to change clothes. The areas shall contain lockers, showers, toilets, handwashing lavatories and space for donning scrub suits and boots. These areas shall be arranged to provide a one (1)-way traffic pattern so that personnel entering from outside the surgical suite can shower, change and move directly into the surgical suite. Similarly, space shall be designed for the removal of scrub suits and boots in the change area so that personnel using it will avoid physical contact with clean personnel.

(P) Space outside the flow of traffic shall be provided for storage of stretchers.

(Q) A janitors' closet containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided exclusively for the surgical suite.

(R) At least one (1) post-anesthesia recovery room shall be provided. This room shall contain a nurses' station, a drug distribution station, clinical gases, handwashing facilities, clinical sink and storage space.

(S) If the program defines an outpatient surgery load, separate areas shall be provided where outpatients can change clothing. This shall include a waiting room, lockers, toilets, handwashing lavatories and a clothing change or gowning area with a traffic pattern similar to that of the staff clothing change area in subsection (8)(O) of this rule.

(T) If outpatient surgical procedures are performed, a separate recovery area with handwashing facilities shall be provided for those patients not subjected to general anesthesia.

(9) Obstetrical Facilities.

(A) If obstetrical facilities are provided, the number of delivery rooms, labor rooms and recovery beds and the size of the service areas shall depend upon the estimated obstetrical workload as described in the program. The post-partum patient area and the obstetrical suite shall be located and arranged to preclude unrelated traffic through the suite.

(B) Each delivery room shall have a minimum clear area of three hundred (300) square feet exclusive of fixed and movable cabinets and shelves. The minimum dimensions shall be sixteen feet (16'). Ceilings shall be at least nine feet six inches (9'6") high. An emergency communication system shall connect the delivery room with the obstetrical suite control station. Separate resuscitation facilities, including electrical outlets, oxygen outlets,

suction outlets and clinical air, shall be provided for newborn infants.

(C) Labor beds shall be provided at the rate of two (2) for each delivery room. In facilities having only one (1) delivery room, two (2) labor rooms shall be provided; and one (1) labor room shall be large enough to function as an emergency delivery room with a minimum of one hundred sixty (160) square feet and shall have at least two (2) oxygen and two (2) suction outlets. All other labor rooms shall be single-bed or two (2)-bed rooms with a minimum clear area of one hundred (100) square feet in single-bed rooms and eighty (80) square feet per bed in two (2)-bed rooms.

(D) Each labor room shall contain a lavatory equipped for handwashing. Each labor room shall have access to a toilet room without entering the corridor. One (1) toilet room may serve two (2) labor rooms.

(E) At least one (1) shower shall be provided for labor room patients.

(F) In facilities having or expecting to have more than one thousand five hundred (1,500) births annually, a recovery room containing not less than two (2) beds shall be provided. This room shall contain handwashing facilities, clinical sink and storage space for supplies and equipment. The room shall be designed to provide at least three feet (3') clear on each side of each recovery bed.

(G) A control station located to permit visual surveillance of all traffic which enters the obstetrical suite shall be provided.

(H) A supervisor's office or station shall be provided.

(I) A high speed autoclave shall be conveniently located to serve all delivery rooms.

(J) A janitors' closet containing a floor receptor or service sink, mop rack and space for equipment shall be provided exclusively for the obstetrical suite.

(K) A nurses' toilet and lounge shall be located near the labor rooms.

(L) Scrub stations shall be provided at the ratio of one (1) for each delivery room.

(M) A soiled workroom or soiled holding room for the exclusive use of the obstetrical suite staff shall be provided. The soiled workroom shall contain a clinical sink or equivalent flushing-type fixture; work counter with double sink, waste receptacle and linen receptacle. A soiled holding room shall be similar to the soiled workroom except that the work counter may be omitted.

(N) A clean workroom or clean supply room shall be provided. A clean workroom with a work counter with sink and storage space for clean and sterile supplies is required when materials are assembled in the obstetrical suite.



(O) An equipment storage room shall be provided. Space shall be assigned for stretcher parking.

(P) Appropriate change areas shall be provided for male and female personnel working within the obstetrical suite. The areas shall contain lockers, showers, toilets, lavatories equipped for handwashing and space for donning scrub suits and boots. These areas shall be arranged to provide a one (1)-way traffic pattern so that personnel entering from outside the obstetrical suite can shower, change and move directly into the obstetrical suite. The space for removal of scrub suits and boots in the change area shall be designed so that personnel using it can avoid contact with clean personnel.

(10) Normal Infant Nursery (if required by program).

(A) The nursery(ies) shall be located in the post-partum nursing unit and as close as possible to the delivery suite. Nurseries shall be located and arranged to preclude unrelated traffic.

(B) No nursery shall open directly into another nursery. If doors are provided to nurseries for emergency evacuation, they shall be operable only from the nursery side and be recessed so as not to swing out into the corridor.

(C) The number of bassinets shall exceed the number of obstetric beds by ten percent (10%) to accommodate multiple births, extended hospitalizations and fluctuating patient loads. When a rooming-in program is used, the total number of bassinets may be reduced, but a nursery must still be provided.

(D) Each nursery shall contain no more than sixteen (16) bassinets.

(E) At least twenty-four (24) square feet of clear floor area shall be provided for each bassinet. At least two feet (2') shall be maintained between each bassinet and an aisle space of at least three feet (3') shall be maintained.

(F) An examining, treatment and work space room with facilities for charting, storage and handwashing shall be provided adjacent to the nursery(ies).

(G) At least one (1) handwashing facility with knee- or foot-action controls and goose-neck spout shall be provided in each nursery.

(H) Space shall be provided for street clothing, cabinets for clean gowns and receptacles for used gowns and other soiled material. This may be a part of the work space mentioned in subsection (10)(F) of this rule if sufficient space is provided.

(I) Observation windows shall be provided between the nursery and the corridor and the

nursery and the workroom. Glazing shall be nonshattering glass.

(J) A janitors' closet shall be provided for the exclusive use of the nursery area. It shall contain a floor receptor or service sink and storage space for equipment and supplies.

(K) A room with handwashing facilities shall be provided where mothers may be given instructions and demonstrations in methods of feeding, bathing and dressing their infants.

(11) Observation Nursery (if required by program).

(A) The observation nursery shall provide for infants suspected of having a condition not conducive to care in the normal infant nursery. Normal infants born at home or in-transit may be admitted to the normal infant nursery. If a private post-partum room is provided, the suspect infant may be housed with the mother until it can be admitted to the normal nursery or transferred to another facility.

(B) Floor space shall be provided at the rate of thirty (30) square feet for each bassinet. At least one (1) observation bassinet shall be provided.

(C) At least one (1) handwashing lavatory with knee- or foot-action controls and goose-neck spout shall be provided in the observation nursery. Work space designed for the normal nurseries may serve the observation nursery.

(12) Continuing care, intermediate care and intensive care nursery facilities shall be designed as required by the functional needs of each program. The minimum floor area per infant station shall be forty (40) square feet.

(13) Pediatric Facilities.

(A) If a hospital's program provides for the design and operation of a pediatric unit, it shall be located where the noise will not intrude on the care of others.

(B) Pediatric patient rooms shall comply with requirements established in subsection (6)(D) of this rule when used for hospital beds. Patient rooms used for cribs shall contain a minimum of sixty (60) square feet of clear area for each crib with no more than six (6) cribs in each room.

(C) The nursing station shall be designed to permit observation and communication between small children and the staff.

(D) Toilet facilities, drinking fountains and furniture shall be designed for small children.

(E) Equipment, such as the nurses' call, shall be simple to operate and switches and plugs for critical equipment shall be located out of reach of young patients.

(F) At least one (1) interview room shall be located in or adjacent to the pediatric unit.

(G) A minimum of two hundred (200) square feet of storage space shall be provided within or adjacent to the unit.

(H) At least one (1) isolation room with toilet, sink, shower or tub shall be provided.

(I) An anteroom with sink wrist controls shall provide access to the isolation room from the corridor.

(J) A nurses' station, with a nurses' lounge, physicians' charting area and a medication room shall be provided. The medication room shall have access only through the nurses' station.

(K) A treatment room shall be provided and equipped with an examination table and counter with sink. A treatment room is not required in those nursing units with all private rooms.

(L) An activity room with at least one hundred fifty (150) square feet of space shall be provided.

(M) Clean and soiled workrooms as described in subsections (5)(D) and (E) of this rule shall be provided.

(N) A janitors' facility shall be provided for each pediatric unit.

(O) Showers shall be provided at a ratio of one (1) shower for each ten (10) beds. In addition, one (1) tub room shall be provided.

(14) Dietary Facilities.

(A) Food service facilities shall be designed and equipped to meet the requirements of the scope of services outlined in the program.

(B) To implement the type of food service selected, the following facilities shall be provided and designed:

1. Receiving area;
2. Storage space including cold storage for four (4) days' supply;
3. Space and equipment for food preparation to facilitate efficient food preparation and to provide for a safe and sanitary environment;
4. Conveniently located handwashing facilities;
5. Space for tray assembly and distribution carts;
6. Dining space;
7. Ware washing space located separately and isolated from food preparation and serving area;
8. Three (3)-compartment sinks for pot washing;
9. Storage areas and washing facilities for cans, carts and mobile tray conveyors;
10. Waste stored so it is inaccessible to insects and rodents and accessible to the outside for pickup or disposal;



11. Office space for manager of dietary service accessible to food production area;

12. Staff toilets with handwashing facilities immediately available;

13. Janitors' closet with floor receptor or a service sink and storage space for equipment; and

14. Dietary facilities which comply with 19 CSR 20-1.010.

(15) Radiology.

(A) Space shall be provided for diagnostic and therapeutic purposes as stated in the program.

(B) As a minimum, the radiology suite shall contain the following:

1. Radiographic room. Radiation protection requirements of X ray and gamma-ray installations shall be in accordance with 19 CSR 20-10.010-19 CSR 20-10.190;

2. Film-processing facilities and film-storage facilities;

3. Office and viewing areas;

4. Toilet with handwashing facilities. A toilet shall be accessible from each fluoroscopy room without entering the general corridor;

5. Dressing area;

6. Waiting room or alcove and a control station; and

7. A holding area for stretcher patients which is out of the direct line of normal traffic.

(16) Laboratory.

(A) Laboratory facilities shall be provided in the hospital or through an effective contract arrangement with another laboratory service acceptable to the Department of Health to meet the workload described in the program.

(B) The following minimum services shall be available in the hospital:

1. Laboratory work counter with sink, vacuum, gas and electric services;

2. Handwashing sink;

3. Storage cabinets;

4. Blood storage facilities with temperature recorder and alarms;

5. Urine collection room with water closet and lavatory; and

6. Blood collection facilities with a work counter, handwashing facilities and space for patient seating.

(17) Pharmacy Facilities.

(A) The size and type of services to be provided in the pharmacy will depend upon the type of drug distribution system to be used in the hospital and whether the hospital proposes to provide, purchase or share pharmacy services with other hospitals or other medical

facilities. This shall be described in the program.

(B) As a minimum, the following functional areas shall be provided:

1. Dispensing area with handwashing facilities;

2. Editing or order review area;

3. Office and record storage area; and

4. Storage areas for bulk and active supplies, a refrigerator, a vault for narcotics, acceptable safe space for volatile liquids and an area for parental admixtures if appropriate.

(18) Outpatient Clinic Services.

(A) The extent of administrative, clinical and diagnostic facilities provided shall be determined by the services contemplated and the estimated patient load as described in the program.

(B) If the facility is designed as an integral part of the hospital and is intended to serve inpatients as well as outpatients, all applicable requirements relating to general hospital facilities shall apply.

(C) Facilities shall be designed and arranged so they are available and accessible to the physically handicapped.

(D) The entrance shall be at grade level and sheltered from the weather.

(E) The lobby shall include wheelchair storage space, reception and information counter or desk, waiting space, public toilet facilities, public telephone and drinking fountain.

(F) General purpose examination rooms shall have minimum floor areas of eighty (80) square feet, excluding spaces such as vestibule, toilet, closet and work counter. A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.

(G) Treatment rooms for minor surgical and cast procedures shall have a minimum floor area of one hundred twenty (120) square feet with a minimum room dimension of ten feet (10'). The minimum floor area shall not include spaces used for vestibule, toilet, closet and work counter. A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.

(H) A nurses' station with a communication system and facilities for charting and storage of clinical records shall be provided.

(I) There shall be a drug storage area.

(J) A clean workroom or clean holding room shall be provided as described in subsection (5)(D) of this rule.

(K) A soiled workroom or soiled holding room shall be provided as described in subsection (5)(E) of this rule.

(19) Central Services.

(A) A separate receiving-decontamination room shall be provided with work space and equipment for cleaning medical and surgical equipment and for disposal of nonreusable material. Handwashing facilities shall be provided. A soiled cart parking space shall be provided.

(B) A clean workroom with space and equipment for sterilizing medical and surgical equipment and supplies shall be provided. At least two (2) pressure sterilizers designed to maintain two hundred fifty degrees Fahrenheit (250°F) or one hundred twenty-one degrees Celsius (121°C) at fifteen pounds (15 lbs.) pressure shall be provided.

(C) Space is to be provided for storage of clean supplies, sterile supplies and clean equipment.

(D) Clean cart-storage space and cart-sanitizing facilities shall be provided.

(20) The area for medical records shall include: review and dictating space; work areas for sorting, recording or microfilming records; storage area for records; and office space for the medical record administrator.

(21) Elevators.

(A) All hospitals having patient-care facilities located on any floor other than the main entrance floor shall have electric or electrohydraulic elevators.

(B) Numbers of Elevators.

1. At least two (2) hospital-type elevators shall be installed where patient-care facilities are located on any floor other than the main entrance floor.

2. In hospitals with more than two hundred (200) beds located on floors other than the main entrance floor, the number of elevators shall be determined from a study of the hospital operation and the estimated vertical transportation requirements.

(C) Details.

1. Cars of hospital-type elevators shall have inside dimensions that will accommodate a patient bed and attendants and shall be at least five feet (5') wide and eight feet (8') deep. The car door shall have a clear opening of not less than four feet (4').

2. Elevators shall be equipped with an automatic leveling device of the two (2)-way automatic maintaining type with an accuracy of plus or minus one-half inch ($\pm 1/2$ ").

3. Elevators, except freight elevators, shall be equipped with a two (2)-way special service switch to permit cars to bypass all landing button calls and be dispatched directly to any floor.

4. Elevator controls, alarm buttons and telephones shall be accessible to wheelchair occupants.



5. Elevator call buttons, controls and door safety stops shall be of a type that will not be activated by heat or smoke.

6. Elevator hoistway doors shall be rated to maintain the integrity of the enclosure.

(22) Linen and Refuse Chutes (if provided).

(A) Service openings to chutes shall not be located in corridors or passageways but shall be located in a room having a fire-resistance construction of not less than one (1) hour. Doors to the rooms shall be not less than three-fourths (3/4)-hour labeled doors and equipped with a closing device.

(B) Service openings for chutes shall have approved self-closing one and one-half (1 1/2)-hour labeled fire doors.

(C) The minimum diameter of gravity chutes shall be not less than two feet (2").

(D) Chutes shall discharge directly into collection rooms separate from the incinerator, laundry or other services. Separate collection rooms shall be provided for trash and for linen. The enclosure construction for the rooms shall have a fire-resistance of not less than one (1) hour. Doors to these collection rooms shall be three-fourths (3/4)-hour labeled fire doors.

(E) Gravity chutes shall extend full diameter through the roof with provisions for continuous ventilation, as well as for fire and smoke ventilation. Openings for fire and smoke ventilation shall have an effective area of not less than that of the chute diameter and shall terminate not less than four feet (4') above the roof and not less than six feet (6') clear of other vertical surfaces.

(23) Dumbwaiters, Conveyors and Material Handling Systems (if provided).

(A) Dumbwaiters, conveyors and material handling systems, excluding pneumatic tubes, shall not open directly into a corridor or exit-way but shall open into a room enclosed by construction having a fire-resistance of not less than one (1) hour and provided with a three-fourths (3/4)-hour labeled fire door with a self-closing device.

(B) Service-entrance doors to vertical shafts containing dumbwaiters, conveyors and material handling systems shall be rated to maintain the integrity of the vertical shaft.

(C) Where horizontal conveyors and material handling systems penetrate fire-rated walls, openings shall be provided with one and one-half (1 1/2)-hour labeled fire doors. Where they penetrate smoke partitions, openings shall be provided with three-fourths (3/4)-hour labeled fire doors.

(24) Fire Prevention and Protection for New and Existing Facilities.

(A) If a facility is located outside of a service area or range of a public fire department, arrangements shall be made to have the nearest fire department respond in the case of fire. A copy of the agreement shall be kept on file in the facility and a copy shall be forwarded to the Department of Health. If the agreement is changed, a copy shall be forwarded to the Department of Health.

(B) General Operating Requirements.

1. Every required exit, exit access or exit discharge shall be maintained free of any obstructions or impediments at all times.

2. Automatic extinguishment systems, fire detection and alarm systems, smoke containment and evacuation systems, exit lighting, fire and smoke doors and other equipment required by this rule shall be tested at intervals not to exceed six (6) months and shall be continuously maintained in proper operating condition.

3. Fire-retardant protective coatings shall be applied to paneling and other materials at intervals as necessary to maintain the required flame-retardant properties.

4. All draperies, curtains and cubicle curtains shall be inherently flame retardant or treated and maintained to retard flame.

5. A written fire safety and evacuation plan shall be available to all personnel. The plan shall provide for the protection of all persons in the event of fire and for their evacuation to areas of refuge in or outside the building when necessary. All employees shall be periodically instructed and kept informed respecting their duties under the plan.

6. Fire drills shall be held at least quarterly for each shift and shall include the simulated use of fire alarm signals and simulation of emergency fire conditions. The movement of patients is not required.

7. Smoking shall be prohibited in any room, ward or compartment where flammable liquids, combustible gases or oxygen are used or stored and in any other hazardous location. The areas shall be posted with NO SMOKING signs.

8. The policies shall prohibit smoking throughout the hospital other than in specific designated areas where smoking may be permitted.

9. Combustible decorations are prohibited unless they have been treated to retard flame.

10. Wastebaskets and other waste containers shall be of noncombustible material.

11. Class A portable fire extinguishers shall be provided and located to provide the capability to fight fires in ordinary combustible material such as wood, cloth, paper and rubber. Class B and Class C portable fire extinguishers shall be provided and located to

provide the capability to fight fires from flammable liquids, gases or grease and in energized electrical equipment. Portable fire extinguishers rated ABC may be used in lieu of Class A, Class B and Class C fire extinguishers. Special situations such as computer rooms may require specific types of fire extinguishers.

12. Fire extinguishers shall be recharged after use or as indicated by inspection.

(C) Life Safety Requirements.

1. New facilities, additions to existing facilities and alterations to existing facilities built in accordance with Chapters 5, 6, 7 and 12 of the *Life Safety Code 1981, Standards for the Installation of Air Conditioning and Ventilating Systems 1978* and *Standard for the Installation of Sprinkler Systems 1980*, all published by the National Fire Protection Association, shall be considered to be in full compliance with this rule if they also comply with subparagraph (24)(C)2.A. of this rule.

2. As a minimum, all new hospitals, additions to existing hospitals and alterations to existing facilities shall comply with the following:

A. An automatic extinguishment system shall be installed in accordance with the *Standard for the Installation of Sprinkler Systems 1980* published by the National Fire Protection Association. Operating rooms, X-ray rooms, delivery rooms, telephone equipment rooms, electrical switchgear and distribution rooms and special care areas may be exempted from sprinkler coverage, provided they are separated from other areas by one (1)-hour fire-resistive construction and provided with smoke detectors;

B. Health care buildings of only one (1) story in height shall be constructed according to one (1) of the following types: I (443); I (332); II (111); II (222); II (000) or III (210) as described in the *Standard Types Building Construction 1979* published by the National Fire Protection Association. All buildings with more than one (1) level below the level of exit discharge shall have all lower levels separated from the level of exit discharge by at least Type II (111) construction;

C. Buildings two (2) stories or more in height shall be of Type I (443), Type I (332) or Type II (222) construction as described in the *Standard Types Building Construction 1979* published by the National Fire Protection Association;

D. Stairways, ramps, elevators hoistways, light or ventilation shafts, chutes and other vertical openings between stories shall be enclosed with construction having at least a one (1)-hour fire-resistance rating in buildings up to and including three (3) stories. In buildings of more than three (3) stories, all



vertical openings shall be enclosed with construction having a two (2)-hour fire-resistance rating;

E. Doors in stair enclosures shall be self-closing and shall be kept in a closed position. Exit doors shall bear a sign visible only in the direction of exit travel stating FIRE EXIT, KEEP DOOR CLOSED;

F. All interior walls and partitions shall be of noncombustible materials;

G. Openings for the passage of ducts, pipes or conduits in floors, walls or partitions that are required to have fire- or smoke-resisting capability shall be protected by filling the space between the penetrating item and the barrier with material which will maintain the rating of the barrier;

H. Types of exits shall be limited to—doors leading directly outside the building, interior stairs, smoke-proof towers, horizontal exits, and exit passageways;

I. At least two (2) exits of the types described in paragraphs (24)(C)2.-4. of this rule shall be provided for each floor or fire section of the building. These exits shall be remote from each other;

J. Horizontal exits.

(I) At least thirty (30) net square feet per patient shall be provided within the aggregated area of corridors, patient rooms, treatment rooms, lounge and other low hazard areas on each side of the horizontal exit. On floors other than patient floors, at least six (6) square feet per occupant shall be provided on each side of the horizontal exit for the total number of occupants in adjoining compartments.

(II) Partitions in a horizontal exit shall have a two (2)-hour fire rating and doors shall have a one and one-half (1 1/2)-hour fire rating.

(III) A single door may be used in a horizontal exit if it serves one (1) direction only and is at least forty-four inches (44") wide.

(IV) A horizontal exit in a corridor eight feet (8') or more in width serving as a means of egress from both sides of the exit shall have the opening protection by a pair of swinging doors each arranged to swing in the opposite direction from the other, with each door leaf being at least forty-four inches (44") wide.

(V) A vertical vision panel twenty-four inches by four inches (24" × 4") of wire glass in steel frame shall be provided in each horizontal exit door. Center mullions are prohibited;

K. Every patient sleeping room shall have an exit access door leading directly to an exit-access corridor unless there is an exit door opening directly to the outside from the room at ground level. One (1) adjacent room, such as a sitting or anteroom, may intervene

if all doors along the means of egress are equipped with nonlockable hardware and if the intervening room is not used to serve as an exit access for more than eight (8) patient sleeping beds. This requirement shall not apply to special care units with supervised nursing care;

L. Aisles, corridors and ramps required for exit access from inpatient areas in a hospital shall be at least eight feet (8') in clear and unobstructed width. Aisles, corridors and ramps in areas not intended for the housing, treatment or use of patients may be a minimum of forty-four inches (44") in clear and unobstructed width;

M. Rooms and any suite of rooms of more than one thousand (1,000) square feet shall have at least two (2) exit access doors remote from each other;

N. Patient sleeping rooms may be subdivided with noncombustible partitions, provided that the arrangement allows for direct and constant visual supervision by nursing personnel. Rooms which are so subdivided shall not exceed five thousand (5,000) square feet. If the space is equipped with an electrically supervised smoke detection system, direct visual supervision is not required;

O. Every corridor shall provide access to at least two (2) approved exits. Means of egress shall not pass through any intervening rooms or spaces other than corridors or lobbies;

P. Every exit or exit access shall be so arranged that no corridor, aisle or passageway has a pocket or dead end exceeding thirty feet (30');

Q. Travel distance between any patient room door and an exit shall not exceed one hundred fifty feet (150'). Travel distance between any point in a room and an exit shall not exceed two hundred feet (200') and travel distance between any point in a hospital sleeping room or suite and an exit access door of that room or suite shall not exceed fifty feet (50');

R. All required exit ramps or stairs shall discharge directly to the outside at grade or be arranged so travel is through an exit passageway discharging to the outside at grade;

S. Doors leading directly to the outside of the building may be subject to locking from the room side provided the door can be opened from the inside without the use of a key;

T. Soiled linen rooms, paint shops, trash collection rooms and rooms or spaces, including repair shops used for the storage of combustible supplies and equipment in quantities deemed hazardous by the Department of

Health, shall be separated from adjacent areas by construction having a one (1)-hour fire-resistance rating;

U. Laboratories employing quantities of flammable, combustible or hazardous materials which are considered a severe hazard shall be protected in accordance with the *Safety Standards for Laboratories in Health-Related Institutions 1980* published by the National Fire Protection Association;

V. Walls and ceilings throughout shall have a Class B interior finish with one (1) exception: individual rooms of not over four (4) patients in capacity may have a Class C interior finish in accordance with Section 6-5 of the *Life Safety Code 1981* published by the National Fire Protection Association;

W. Floors throughout the facility shall have a Class II interior floor finish as described in Section 6-5 of the *Life Safety Code 1981* published by the National Fire Protection Association;

X. Corridors shall be separated from all other areas by partitions. Partitions shall be of noncombustible construction and may terminate the suspended ceiling. Corridor partitions shall form tight joints with the ceiling;

Y. Vision panels in corridor partitions shall be constructed to resist the passage of smoke;

Z. Doors in corridor partitions shall be constructed to resist the passage of smoke and shall be provided with latches of a type suitable for keeping the door tightly closed;

AA. Smoke barriers shall be provided, regardless of building construction type, to divide into at least two (2) compartments every story used by inpatients for sleeping or treatment or any story having an occupant load of fifty (50) or more persons and to limit on any story the length and width of each smoke compartment to no more than one hundred fifty feet (150'). Horizontal exits may serve as smoke barriers;

BB. Smoke barriers shall have a fire-resistance rating of at least one (1) hour;

CC. Doors in smoke barriers shall be substantial doors, such as one and three-fourth inches (1 3/4") thick solid-bonded core wood or construction that will resist fire for at least twenty (20) minutes. Each door leaf shall have a wireglass vision panel not exceeding one thousand two hundred ninety-six (1,296) square inches in metal frames. Corridor openings in smoke barriers shall be protected by a pair of swinging doors, each door to swing in a direction opposite from the other. The minimum door leaf width shall be forty-four inches (44"); and

DD. Doors in smoke barriers shall be self-closing or they may be held open by an



automatic release device which shall be connected to a manual alarm system, an automatic smoke detection system and a complete automatic fire-extinguishing system. Activation of any of these three (3) systems shall initiate the closing action of all doors by zone or throughout the entire facility.

(25) Construction.

(A) Every building and every portion of it shall be designed and constructed to sustain all dead and live loads in accordance with accepted engineering practices and standards.

(B) Foundations shall rest on natural solid bearing if a satisfactory bearing is available at reasonable depths. Proper soil-bearing values shall be established in accordance with recognized standards. If solid bearing is not encountered at practical depths, the structure shall be supported on driven piles or drilled piers designed to support the intended load without detrimental settlement; except that one (1)-story buildings may rest on a fill designed by a soils engineer. When engineered fill is used, site preparation and placement of fill shall be done under the direct full-time supervision of the soils engineer. The soils engineer shall issue a final report on the compacted fill operation and certify its compliance with the job specifications. All footings shall extend to a depth not less than one foot (1') below the estimated maximum frost line.

(26) Electrical Systems.

(A) General Requirements.

1. Materials used in installations shall be listed as complying with standards of Underwriters' Laboratories, Inc. or a similar recognized agency where the standards have been established.

2. After completion, all electrical systems shall be tested and demonstrated to show satisfactory compliance with the specified performance criteria and installation requirements. A written record of the results of performance tests made on special systems and equipment shall be furnished to the owner. Special systems shall include: high voltage cable "hi-pot" direct current test, isolated power systems leakage currents, conductive floors resistance values, equi-potential grounding systems continuity tests, fire alarm and smoke detection systems, emergency and disaster loud-speaker systems, patient emergency call system, all other alarm systems, and standby emergency generator power, lighting and automatic transfer systems.

(B) Two (2) separate sources for electrical supply, a normal source and an alternate source, shall be provided. The normal source

shall supply full-load requirements continuously with the alternate source supplying power on an emergency basis to selected circuits when normal power supply is interrupted. One (1) alternate source shall be an on-site engine-driven generator facility utilizing on-site fuel.

(C) Switchgear and Switchboards.

1. Incoming line switchgear for primary voltage electrical services or distribution switchboards for secondary voltage electrical services shall consist of dead-front metal enclosed assemblies of automatic circuit breakers or fused switches arranged to provide service-disconnecting means and over-current and short-circuit protection for entrance feeders and for distribution feeder conductors.

2. Switchgear, switchboards, panelboards, switches and other equipment of the main service and distribution systems for both normal and emergency power shall be installed in separate dry, ventilated rooms which have a one (1)-hour fire rating and are reserved exclusively for electrical equipment. Piping of utility service systems carrying water or other liquids shall not be installed in the electrical equipment room.

3. Ratings of switchgear and switchboard assemblies shall ensure that maximum available short-circuit currents are safely interrupted.

(D) Panelboards.

1. Panelboards supplying lighting and receptacle and appliance-branch circuits shall be located on the same floor as the loads they serve. Each outlet shall be located no farther than one hundred feet (100') from its supplying panelboard.

(E) Standby Emergency Electric Service.

1. An on-site engine-driven emergency generator utilizing on-site fuel shall be provided to deliver electrical power during an interruption of normal power supply. There shall be sufficient fuel on site to ensure continuous operation for twenty-four (24) hours.

2. Engine-generators shall be installed in separate dry, ventilated rooms which have a one (1)-hour fire rating and are reserved exclusively for the engine-generator system equipment. Piping of utility service systems carrying water or other liquids which are not serving the engine-generator system shall not be installed within the engine-generator room.

3. Standby emergency generators shall be installed and arranged so that full voltage and frequency is available and supplying power to emergency loads within ten (10) seconds after normal power is interrupted.

4. Automatic emergency electric service shall be provided to elements of the distribution system as follows:

A. Circuits essential for the safety of patients and personnel shall include:

(I) Illumination of means of egress;

(II) Illumination for exit signs and exit directional signs;

(III) Task illumination for major electrical equipment, major mechanical equipment, pumps, elevator machinery, telephone switchboard and standby generator;

(IV) Alarm systems including fire alarms activated by manual stations, water-flow alarm devices of the sprinkler system, fire and smoke detecting systems and alarms required for blood banks and medical gas systems;

(V) Paging or speaker systems if intended for communication of emergency and disaster calls during outage of normal power. Radio transceivers where installed for emergency use shall be capable of operating for at least one (1) hour upon total failure of both normal and emergency power; and

(VI) General illumination and at least one (1) receptacle in the vicinity of standby generators;

B. Circuits essential to care, treatment and protection of patients shall include:

(I) Task illumination and at least one (1) receptacle serving the following areas and functions related to patient care: anesthetizing locations, infant nurseries with a minimum of one (1) receptacle for each station, medication preparation areas, pharmacy dispensing areas, psychiatric patient areas, treatment rooms, nurses station, angiographic room, cardiac catheterization room, emergency treatment rooms, human physiology laboratories and the headwall of each patient room; and

(II) Task illumination and all receptacles for—operating rooms, delivery rooms and labor rooms and recovery rooms, special care units, acute hemodialysis rooms, post-operative recovery areas, nurses' call systems, bone and tissue banks, telephone equipment room, closets and blood banks;

C. Power circuits which serve the following equipment shall be arranged for automatic connection to the standby emergency service: central suction systems serving medical and surgical functions; clinical air systems serving medical and surgical functions, if installed; sump pumps and other equipment required to operate for the safety of major equipment; fire pump, if installed; and smoke ventilation and evacuation systems, if installed; and

D. Power circuits shall be arranged for either delayed automatic or manual



connection to the standby emergency electrical service for the following equipment:

(I) Equipment for comfort heating of operating, delivery, labor and recovery rooms; special care areas; nurseries; and general patient rooms. If the comfort heating system of a facility utilizes electricity as the energy source, standby emergency electric service shall be connected to the heating equipment of rooms, corridors and other spaces in which general care patients are located;

(II) One (1) or more elevators selected to provide service to all floors. Throw-over facilities shall be provided to permit temporary operation of all elevators for the release of patients or other persons from elevator cabs which may be trapped between floors;

(III) Supply and exhaust ventilating systems for surgical and obstetrical delivery suites, infant nurseries, isolation rooms, emergency treatment spaces and laboratory fume hoods;

(IV) Hyperbaric and hypobaric facilities, if provided; and

(V) Automatically operated doors.

5. Receptacles connected to the standby emergency electrical system shall be permanently and distinctively identified in a uniform manner.

6. All wiring for equipment and systems essential to the safety of patients and personnel and for care, treatment and protection of patients shall be kept entirely independent of all other wiring, and equipment and shall not enter the same raceways, boxes or cabinets with other wiring, except when located in transfer switches and in exit or emergency lighting fixtures or in a common junction box attached to exit or emergency lighting fixture.

(F) Nurses' Call Systems.

1. Patient nursing units.

A. In general, patient areas and each patient room shall be served by at least one (1) calling station and each bed shall be provided with a call button. Two (2) call buttons serving adjacent beds may be served by one (1) calling station.

B. A nurses' call emergency station button or switch shall be provided for patients' use at each toilet, bath, sitz bath and shower room intended for patient use. The station shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord will satisfy this requirement.

C. Calls shall register at a nurse station or other floor unit station to indicate location of call placed and shall actuate a visible signal in the corridor at the patients' room door, in the clean workroom, the soiled

workroom and the nourishment station of the nursing unit.

D. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections.

E. In rooms containing two (2) or more calling stations, indicating lights shall be provided at each station.

F. Nurses' calling systems which provide two (2)-way communication shall be equipped with an indicating light at each calling station which lights and remains lighted as long as the voice circuit is operating.

2. In special care units such as intensive care or coronary care where patients are under constant surveillance, the nurses' calling system may consist of a bedside station that will actuate an audible and visual signal that can be readily observed.

3. Patient treatment specialty areas.

A. Emergency calling stations which may be used to summon assistance shall be provided in—operating rooms; delivery and labor rooms, recovery rooms, nurseries and special care units.

B. Each toilet intended for patient use within diagnostic and treatment areas shall be provided with an emergency call station which shall activate an audible and visual signal within the unit.

(G) Lighting Systems.

1. All spaces occupied by people, machinery and equipment within buildings, approaches to buildings and parking lots shall be equipped with artificial lighting.

2. Operating and delivery rooms shall have general lighting in addition to local lighting provided by special lighting units at the surgical and obstetrical tables. Each fixed special lighting unit at the tables, except for portable units, shall be connected to an independent circuit.

3. Nursing unit corridors shall have general illumination with provisions for reduction of light level at night.

4. Emergency lighting requirements shall be in accordance with paragraphs (26)(E)1.-4. of this rule and the *Standard for Essential Electrical Service for Health Care Facilities 1977* published by the National Fire Protection Association.

(H) Convenience Receptacles.

1. Patient areas.

A. As a minimum, each patient room shall have one (1) duplex grounding-type receptacle located in the headwall on each side of each bed. One (1) duplex receptacle between beds of a two (2)-patient room may satisfy requirements for one (1) side of each bed. One (1) duplex grounding-type receptacle shall be provided for television, if used;

one (1) for the electric bed, if used; and one (1) for each inside wall.

B. Nurseries shall have not less than one (1) duplex grounding-type receptacle for each bassinets station.

C. Receptacles in each pediatric and psychiatric room shall be of the safe type or shall be provided with an on-off switch control located outside the patient sleeping room at a controlled or supervised location.

2. Corridors.

A. Duplex grounding-type receptacles of at least twenty (20) amperes for general use and for floor cleaning equipment shall be located approximately fifty feet (50') apart in all corridors.

B. Receptacles in corridors of pediatric and psychiatric units shall be of the safety type or shall be controlled by switches located at a nurses' station or other secure location.

3. Anesthetizing locations.

A. Each operating and delivery room shall have at least three (3) receptacles. Receptacles in anesthetizing areas shall comply with the *Standard for Inhalation Anesthetics 1980* published by the National Fire Protection Association.

B. In each anesthetizing location where line voltage mobile X ray is used, an additional receptacle distinctively marked for X-ray use shall be provided.

C. All electrical equipment and devices, receptacles and wiring shall comply with the *Standards for Inhalation Anesthetics 1980* published by the National Fire Protection Association.

4. Special areas.

A. X-ray installations. Fixed and mobile X-ray equipment installations shall conform to Article 517 of *The National Electrical Code 1981* published by the National Fire Protection Association.

B. X-ray film illuminator units. At least one (1) double unit shall be installed in each operating room and in the X-ray viewing room of the radiology department.

C. Ground-fault interrupters. The electrical circuit(s) to equipment in wet areas shall be provided with five (5) milliampere ground fault interrupters. Wet areas include hydrotherapeutic tanks, if used, hydro-massage tubs, if used, and other locations identified by hospital administration. Where ground fault interrupters are used in critical areas, provision shall be made to ensure that other essential equipment will not be affected by a single interruption.

D. When the program requires a special grounding system to be installed in special care areas, the system shall comply with Article 517 of *The National Electrical Code*



1981 published by the National Fire Protection Association.

(I) Fire Detection and Alarm Systems.

1. Approved, electrically supervised manual and automatic detection and alarm systems shall be provided in accordance with Chapter 12 of *Life Safety Code 1981* published by the National Fire Protection Association.

2. Manual alarm initiating devices shall be installed in the following locations: each exit from the fire area but no farther than one hundred fifty feet (150') from any point on the floor and installations shall be located so that no more than one hundred fifty feet (150') of horizontal distance on the same floor must be traveled to reach a station; at each nurses' station or other patient care control station and at the telephone switchboard.

A. Automatic smoke detectors shall be installed in all corridors throughout the building spaced no more than seventy-five feet (75') apart and no more than thirty feet (30') from the ends of corridors. The automatic smoke detection system shall be electrically interconnected with the fire alarm system and the sprinkler system.

B. Water-flow switches of the sprinkler systems shall be connected into the fire alarm system to function as an automatic alarm initiating device.

3. Alarm signals shall provide audible indication of fire and shall be located and of a character that they can be effectively heard in all areas of the building above the ambient noise level of normal occupancy conditions.

4. Operation of any alarm initiating device, either manual or automatic, shall cause the following actions to automatically occur within a building: all alarms shall be activated on the fire floor, on the floor above and on the floor below; alarms shall be activated in at least one (1) continuously supervised location; an alarm shall be transmitted to the fire department or to an approved central station located outside the premises; zone annunciators shall be energized to indicate location of alarm initiation; smoke doors shall release and close on the fire floor, on the floor above and on the floor below; smoke dampers shall release and close on the fire floor to isolate the smoke zone and smoke ventilation and evacuation systems, if installed, shall be activated.

5. Zone annunciators shall be located at the switchboard and in at least one (1) continuously supervised location.

6. The smoke ventilation and evacuation system, if installed, shall be designed so operation of a manual pull station will not actuate it.

(27) Mechanical Systems.

(A) General Requirements.

1. Prior to completion and acceptance of the facility, all heating, ventilating and air-conditioning systems shall be tested, balanced and operated to demonstrate to the owner or his/her representative that the installation and performance of these systems conform to the requirements of the plans and specifications.

2. Upon completion of the contract, the owner shall be furnished with a complete set of manufacturer's operating, maintenance and preventive maintenance instructions and parts lists and procurement information with numbers and description for each piece of equipment and test results. The owner also shall be provided with instruction in the operational use of systems and equipment.

3. The heating, ventilating and air-conditioning system shall be capable of providing the temperatures and humidifies in the following areas:

Area Designation	Temperature		Relative Humidity (%)	
	F°	C°	Min.	Max.
	Operating Rooms	68-76	20-24	50
Delivery Rooms	70-76	21-24	50	60
Recovery Rooms	75	24	30	60
Intensive Care Rooms	72-78	22-26	30	60
Nursery Units	75	24	30	60
Special Care Nursery Unit	75-80	24-27	30	60
Patient Care, Treatment, Diagnostic and Related Areas	72-78	22-26	30	60

4. The heating system shall be capable of maintaining an indoor winter temperature of seventy-five degrees Fahrenheit (75°F) in all other areas occupied by inpatients. The heating system shall be capable of maintaining an indoor winter temperature of seventy-two degrees Fahrenheit (72°F) in all nonpatient areas.

5. The boiler plant shall have the capacity to supply the normal utility requirements of all systems and equipment.

6. The number and arrangement of boilers shall be such that when one (1) boiler breaks down or is shut down for routine maintenance the remaining boiler(s) shall be capable of carrying the normal building load.

7. The boilers may be fired by coal, fuel oil, natural gas, liquid propane gas or electricity. All boilers shall be suitable for dual fuel firing with the standby fuel stored on-site. The amount of on-site fuel storage shall be adequate for ninety-six (96) hours of con-

tinuous firing at design load. In the case of electric boilers or total electric installations, the dual fuel requirement may be waived depending on the type of electric service and sources of supply to the building.

8. If coal-fired boilers are used, stack effluent shall comply with both state and federal environmental standards.

9. Boiler feed pumps, heating circulating pumps, condensate return pumps and fuel oil pumps shall be furnished in duplicate to provide normal and standby service.

10. Steam boiler plants operating above twenty pounds per square inch (20 psi) shall be designed to supply zero (0) oxygen boiler feedwater to the boilers.

11. Boiler rooms shall be provided with sufficient outdoor air to maintain combustion rates of equipment and to limit temperatures in working stations to no more than ninety-seven degrees Fahrenheit (97°F).

(B) Heating, Ventilating and Air-Conditioning Systems.

1. All air supply, return and exhaust systems shall be mechanically operated.

2. All heating, ventilating and air-conditioning systems shall be designed to maintain general pressure relationships and ventilation rates as shown in Table 1 in paragraph (27)(B)3. of this rule.

3. See Table 1.

4. Constant volume systems shall be used in all areas of the hospital listed in Table 1 in paragraph (27)(B)3. of this rule; variable air-volume systems may be used in areas not listed in this table and where direct patient care is not affected. Consideration may be given to special design innovations in areas of Table 1, provided that pressure relationship as an indication of direction of air flow and total number of air changes during occupied periods in those areas listed in Table 1 are maintained.



Table 1
General Pressure Relationship and Ventilation
of Certain Hospital Areas

Area Designation	Pressure Relationship to Adjacent Areas	Minimum Air Changes of Air per Hour Supplied to Room	Minimum Total Air Changes per Hour Supplied to Room	All Air Exhausted Directly to Outdoors	Recirculated Within Room Units
Operating Room (for recirculating air system)	P	5	25	Optional	No
Operating Room (all-outdoor-air system)	P	15	15	Yes	No
Trauma Room	P	5	12	Optional	No
Examination and Treatment Room	E	2	6	Optional	Optional
Delivery Room	P	5	12	Optional	No
Nursery Unit	P	5	12	Optional	No
Recovery Room	P	2	6	Optional	No
Intensive Care	P	2	6	Optional	No
Patient Room	E	2	2	Optional	Optional
Patient Room Corridor	E	2	2	Optional	Optional
Isolation Room		2	6	Yes	No
Isolation Room—Alcove or Anteroom		2	10	Yes	No
Examination Room	E	2	6	Optional	Optional
Medication Room	P	2	4	Optional	Optional
Pharmacy	P	2	4	Optional	Optional
Treatment Room	E	2	6	Optional	Optional
X-ray Fluoroscopy	N	2	6	Yes	No
X-ray, Other Diagnostic Rooms	V	2	6	Optional	Optional
Physical Therapy and Hydrotherapy	N	2	6	Optional	Optional
Soiled Workroom or Soiled Holding	N	2	10	Yes	No
Clean Workroom or Clean Holding	P	2	4	Optional	Optional
Autopsy	N	2	12	Yes	No
Darkroom	N	2	10	Yes	No
Nonrefrigerated Body Holding Room	N	Optional	10	Yes	No
Toilet Room	N	Optional	10	Yes	No
Bedpan Room	N	Optional	10	Yes	No
Bathroom	N	Optional	10	Yes	No
Janitor's Closet	N	Optional	10	Yes	No
Sterilizer Equipment Room	N	Optional	10	Yes	No
Linen and Trash Chute Rooms	N	Optional	10	Yes	No
Laboratory, General	N	2	6	Optional	Optional
Laboratory, Media Transfer	P	2	4	Optional	No
Food Preparation Centers	E	2	10	Yes	No
Warewashing	N	Optional	10	Yes	No
Dietary Day Storage	V	Optional	2	Optional	No
Laundry, General	V	2	10	Yes	No
Soiled Linen Sorting and Storage	N	Optional	10	Yes	No
Clean Linen Storage	P	Optional	2	Optional	Optional
Anesthesia Storage Central Services	V	Optional	8	Yes	No
Soiled or Decontamination Room	N	2	6	Yes	No
Clean Workroom	P	2	4	Optional	Optional
Equipment Storage	V	Optional	2	Optional	Optional

P = Positive N = Negative E = Equal V = May Vary

For maximum energy conservation, use of a recirculated filtered air system is preferred. An all-outdoor-air system may be used, where required by local codes, provided that appropriate heat recovery procedures are utilized for exhaust air. Heat recovery systems should be utilized where appropriate, especially for those areas where all air is required to be exhausted to the outside. Requirements for outdoor air changes may be deleted or reduced and total air changes per hour supplied may be reduced to 25% of the figures listed when the affected room is unoccupied and *unused* provided that indicated pressure relationship is maintained. In addition, positive provisions such as an interconnect with room lights must be included to insure that the listed ventilation rates including outdoor air are automatically resumed upon reoccupancy of the space. This exception does not apply to certain areas such as toilets and storage which would be considered as in use even though unoccupied.

Rooms normally used for diagnostic X rays and only *occasionally* for fluoroscopic procedures may utilize recirculated air without requirements for all air to be exhausted directly to outdoors.



5. Wall intake boxes are prohibited as an acceptable means of introducing the required two (2) air changes of outside air into patient rooms. If incremental, electrohydraulic or fan coil units are used, a separate system of one hundred percent (100%) outside air properly tempered year-round shall be used to introduce outside air to the patient rooms. This air quantity shall equal the amount of air being exhausted from the patient room's toilet room, but in no case shall it be less than two (2) air changes per hour. If incremental heating, ventilating and air conditioning units are used, the ventilating air passages shall be permanently closed.

6. Outside air intakes shall be located no less than twenty-five feet (25') from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical clinical suction discharges and plumbing vent stacks or from areas which may collect vehicular exhaust and other noxious fumes. Plumbing and vacuum vents that terminate above the level of the top of the air intake may be located as close as ten feet (10'). The bottom of outside air intakes serving central systems shall be located no less than six feet (6') above ground level, or if installed above the roof, no less than three feet (3') above the roof level.

7. All air supplied to operating rooms, delivery rooms and nurseries shall be delivered at or near the ceiling of the area served. All air returned from operating rooms, delivery rooms and nurseries shall be removed near the floor level.

8. At least two (2) return air outlets located remote from each other shall be provided in each operating and delivery room.

9. The bottoms of ventilation (supply and return) openings shall not be less than six inches (6") above the floor of any room except as indicated in paragraph (27)(B)7. of this rule.

10. Corridors shall not be used to supply air to or exhaust air from any room, except that air from corridors may be used to ventilate bathrooms, toilet rooms, janitors' closets and small electrical or telephone closets opening directly onto corridors provided that ventilation can be accomplished by undercutting of doors.

11. Medical isolation rooms and intensive care rooms may be ventilated by induction units if the induction units contain only a reheat coil and if only the primary air supplied from a central system passes through the reheat coil.

12. All central ventilation of air-conditioning systems shall be equipped with filters having efficiencies no less than those specified in Table 2 in paragraph (27)(B)16. of this

rule. Where two (2) filter banks are required, filter bank number 1 shall be located upstream of the air-conditioning equipment and filter bank number 2 shall be downstream of the supply fan, recirculating spray water systems, water reservoir-type humidifiers and cooling coils. Drift eliminators shall be used downstream of cooling coils to prevent the carry-over of moisture from the cooling coils to filter bank number 2. Where terminal filters are used in operating rooms and delivery rooms, the second filter bank may be located immediately downstream of the first filter bank.

13. Where only one (1) filter bank is required, it shall be located upstream of the air-conditioning equipment unless an additional pre-filter is employed. In this case, the pre-filter shall be upstream of the equipment and the main filter may be located farther downstream.

14. Filter frames shall be durable and carefully dimensioned and shall provide an airtight fit with the enclosing ductwork. All joints between filter segments and the enclosing ductwork shall be gasketed or sealed to provide a positive seal against air leakage.

15. A manometer shall be installed across each filter bank serving sensitive areas or central air systems.

Table 2
Filter Efficiencies for Central Ventilation and Air-Conditioning Systems in General Hospitals

Area Designation	Minimum Number of Filter Beds	Filter Efficiencies	
		Filter Bed #1	Filter Bed #2
		(%)	(%)
Operating Rooms, Delivery Rooms, Nurseries, Recovery Rooms and Intensive Care Units	2	25	90
Patient Care, Treatment, Diagnostic and Related Areas	2	25	90*
Food Preparation Areas and Laundries	1	80	—
Administrative, Bulk Storage and Soiled Holding Areas	1	25	—

*May be reduced to 80% for systems using all-outdoor-air.

17. Ducts which penetrate construction intended for X-ray or other ray protection shall not impair the effectiveness of the protection.

18. Fire and smoke dampers shall be constructed, located and installed in accordance with the *Standard for the Installation of*

Air Conditioning and Ventilating Systems 1978 published by the National Fire Protection Association. All fire and smoke dampers shall be accessible for servicing.

19. Supply, return air and exhaust ducts which pass through a smoke partition shall be provided with dampers at the partition and controlled to close automatically to prevent flow of air or smoke when a smoke detector located in the duct or at the smoke partition is actuated. Dampers shall be equipped with remote control reset devices. On high-velocity systems, a time delay shall be provided so the fan will be stopped prior to damper closing. Engineered smoke evacuation systems will be considered for approval on a case-by-case basis.

20. If the air changes required in Table 1 in paragraph (27)(B)3. of this rule do not provide sufficient air for use by hoods and safety cabinets, additional make-up air shall be provided as necessary to maintain the required room pressure relationship.

21. Laboratory hoods shall meet the following general requirements: have an average face velocity of not less than seventy-five feet (75') per minute, be connected to an exhaust system which is separate from the building exhaust system, have an exhaust fan located at the discharge end of the system and have an exhaust duct system of noncombustible corrosion-resistant material designed to meet the planned usage of the hood.

22. Each laboratory hood which processes infectious or radioactive materials shall have a minimum face velocity of one hundred feet (100') per minute, shall be connected to an independent exhaust system shall have filters with a ninety-nine and ninety-seven one-hundredths percent (99.97%) efficiency in the exhaust stream; and shall be designed and equipped to permit the safe removal, disposal and replacement of contaminated filters.

23. Duct systems serving hoods in which radioactive strong oxidizing agents are used shall be constructed of stainless steel for a minimum distance of ten feet (10') above the hood and shall be equipped with wash-down facilities.

24. Exhaust hoods in food preparation centers shall comply with the requirements of *The Standards for the Installation of Equipment for the Removal of Smoke and Grease-Laden Vapors From Commercial Cooking Equipment 1980* published by the National Fire Protection Association. All hoods and cooktop surfaces shall be equipped with automatic fire suppression systems, automatic fan controls and fuel shutoff.

25. The ventilation system for anesthesia storage rooms shall comply with *The*



Standard for Inhalation Anesthetics 1980 published by the National Fire Protection Association.

(C) Piping systems shall be run in spaces that are generally accessible for maintenance and repair. Piping shall be installed with adequate provision for expansion and contraction and securely supported from the structure.

1. Reverse return piping systems shall be utilized where necessary to maintain water temperatures.

2. Connections between dissimilar metals shall be equipped with insulating unions or flanges.

3. Valves shall be installed in branches from mains or risers in order to isolate sections of both the hot or chilled water systems. All risers shall be equipped with drain valves and vent cocks.

4. Valves shall be installed at all equipment connections for ease in servicing equipment.

(D) Duct systems shall be fabricated and installed in accordance with the *Standard for Installation of Air Conditioning and Ventilating Systems 1978* published by the National Fire Protection Association.

(E) Insulation.

1. Insulation shall be installed in accordance with the *Commercial and Industrial Insulation Standards Manual* of the Midwest Insulating Contractors Association (MICA).

2. Insulation shall be provided for the following: boilers, smoke breeching and stacks; steam supply and condensate return piping; hot water piping above one hundred degrees Fahrenheit (100°F) and all hot water heaters, generators and converters; chilled water piping, refrigerant piping and other process piping and equipment operating with fluid temperatures below the ambient dew point; water supply and drainage piping on which condensation may occur; air ducts and casings with outside surface temperature below the ambient dew point or temperature above eighty degrees Fahrenheit (80°F); and other piping, ducts and equipment necessary to maintain the efficiency of the systems.

3. Insulation on cold surfaces shall include an exterior vapor barrier.

4. Insulation, including finishes and adhesives on the exterior surfaces of ducts, pipes and equipment, shall have a flame spread rating of twenty-five (25) or less and a smoke developed rating of fifty (50) or less in accordance with the *Standard for Installation of Air Conditioning and Ventilating Systems 1978* published by the National Fire Protection Association.

5. Linings and coatings, adhesives and insulation on exterior surfaces of pipes and ducts in building spaces used as air supply

plenums shall have a flame spread rating of twenty-five (25) or less and a smoke developed rating of fifty (50) or less as determined by an independent testing laboratory in accordance with the *Standard for Surface Burning Characteristics of Building Materials 1979* published by the National Fire Protection Association.

6. Duct linings shall not be used in systems supplying operating rooms, delivery rooms, recovery rooms, nurseries, isolation rooms and intensive care units unless terminal filters of at least ninety percent (90%) efficiency are installed downstream of the linings.

(F) All new hospitals shall be equipped with central-piped oxygen and clinical suction systems. Consideration also shall be given to installing central-piped nitrous oxide, nitrogen, clinical air, carbon dioxide and natural gas.

1. All medical gases shall be installed in accordance with the *Standard For Non-flammable Medical Gas Systems 1977* published by the National Fire Protection Association.

2. All medical gas piping shall be identified in some manner by the following color code: oxygen—green, nitrous oxide—light blue, clinical air—yellow, carbon dioxide—gray, nitrogen—black, and clinical suction—yellow.

3. Oxygen and clinical suction outlets shall be installed as outlined in Table 3.

**Table 3
Station Outlets for Oxygen
and Vacuum (Suction) Systems**

Location	Clinical	
	Oxygen	Suction
Patient Room for Adult Medical, Surgical and Postpartum Care and for Pediatrics	A	A
Examination and Treatment Room for Nursing Unit	B	B
Patient Room for Intensive Care	C	C
Nursery and Pediatric Nursery	A	A
General Operating Room	F	F
Cystoscopy and Special Procedure Room	D	D
Recovery Room for Surgical and Obstetrical Patients	E	E
Delivery Room	F	G
Labor Room	A	A
Treatment Room for Emergency Care	D	D
Autopsy Room	—	D
Anesthesia Workroom	—	D

A—One outlet accessible to each bed. One outlet may serve two beds.

B—One outlet. Portable equipment for the administration of oxygen and suction may be considered acceptable in lieu of a piped system.

C—Two outlets for each bed or provide one outlet with Y fitting.

D—One outlet.

E—One outlet for each bed.

F—Two outlets.

G—Three outlets.

4. A separate dedicated waste anesthesia gas exhaust system shall be provided, except nonflammable waste anesthesia gases may be connected into the clinical suction system provided the anesthesia gases are not detrimental to the clinical suction pumps and the pumps are vented directly to the atmosphere.

(G) Plumbing Systems.

1. All plumbing systems shall be designed and installed in accordance with applicable state and local codes.

2. Plumbing fixtures.

A. Plumbing fixtures shall be of non-absorptive acid-resistant material.

B. The water supply spout for a lavatory and sink located in patient care area shall be mounted so that its discharge point is a minimum distance of five inches (5") above the rim of the fixture. All fixtures used by medical and nursing staff and all lavatories used by patients and food handlers shall be trimmed with valves which can be operated without the use of hands. When blade handles are used for this purpose, they shall not exceed four and one-half inches (4 1/2") in length, except that handles on scrub sinks and clinical sinks shall be not less than six inches (6") long. All lavatories and sinks shall be equipped with stop valves.

C. Clinical sinks shall have a bedpan flushing device and shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

D. Showers and tubs shall be provided with nonslip surfaces.

E. All scrub sinks shall be equipped with knee- or foot-operated controls.

F. Water closets in patient areas shall be quiet operating types.

G. Stools in patient, diagnostic and treatment areas shall be the elongated bowl type with nonreturn stops, backflow preventers and silencers. Seats shall be the split type.

H. Bedpan flushing devices shall be provided in each patient toilet room except those in psychiatric units, alcohol abuse units and other ambulatory care facilities.

3. Water supply systems.



A. The water supply systems shall be designed to supply water at sufficient pressure to operate all fixtures and equipment during maximum demand periods.

B. Each water service main, branch main, riser and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture.

C. Backflow preventers and vacuum breakers shall be installed on hose bibbs, laboratory sinks, janitors' sinks, bedpan-flushing attachments, autopsy tables and on all other fixtures to which hoses or tubing can be attached.

D. The water supply system shall be designed to provide hot water at each hot water outlet at all times. Hot water at showers and bathing facilities shall not exceed one hundred ten degrees Fahrenheit (110°F). Hot water at handwashing facilities shall not exceed one hundred twenty degrees Fahrenheit (120°F).

4. Hot water-heaters and tanks. Hot water heating equipment shall have sufficient capacity to supply water at the temperatures and amounts indicated in Table 4. Water temperatures are to be taken at hot water point of use of inlet to processing equipment.

**Table 4
Hot Water Use**

	Clinical	Dietary	Laundry
Gallons (per hour per bed)	6 1/2	4	4 1/2
Liters (per second per bed)	.007	.004	.005
Temperatures (°F)	110	120*	160**
Temperature (°C)	43	49*	71**

*The rinse water temperature of automatic warewashing equipment shall be one hundred eighty degrees Fahrenheit (180°F).

**Sufficient hot water is to be delivered to the laundry to maintain this temperature in the washing machine during the entire wash and rinse period.

5. Consideration shall be given to the use of water softeners to soften domestic hot water and boiler water make-up whenever the water supply exceeds five (5) grain hardness.

6. Drainage systems.

A. Drain lines from sinks in which acid wastes may be poured shall be fabricated from an acid-resistant material.

B. Drain lines serving automatic blood cell counters shall be of carefully selected material to prevent undesirable chemical reactions between blood count wastes and plumbing system materials such as copper, lead, brass and solder.

C. Drainage piping shall not be installed in an exposed location in operating

and delivery rooms, recovery rooms, nurseries, food preparation centers, food service facilities, food storage areas and other critical areas; special precautions shall be taken to protect any of these areas from possible leakage or condensation from necessary overhead drainage piping systems. These special precautions include requiring noncorrosive semi-circular drip troughs with a minimum four inch (4")-outside diameter to be installed under the drainage pipe in the direction of slope to a point where the pipe leaves the protected space and terminates at that point—usually at a wall. The trough shall be supported with noncorrosive strap hangers and screws from the pipe above. Trough joints and hanging screw penetrations shall be sealed to maintain watertight integrity throughout.

D. Floor drains shall not be installed in general operating and delivery rooms. Flushing rim-type floor drains may be installed in cystoscopic operating rooms.

E. Building sewers shall discharge into a community sewerage system when available. If such a system is not available, a facility providing sewage treatment shall conform to 10 CSR 20-6.010.

(28) Service Facilities.

(A) Space shall be provided for the maintenance engineer's office, maintenance shop and storage for building maintenance supplies.

(B) Service entrances to receiving rooms shall be protected from the weather.

(C) General storage space excluding space for receiving and the purchasing office shall be provided at the rate of twenty (20) square feet per bed for the first four hundred (400) beds and ten (10) square feet per bed for all additional beds. Off-site storage space is acceptable, however, one-half (1/2) of the required storage space shall be located in the hospital. General storage shall be concentrated in one (1) area.

(D) Space and facilities shall be provided for the sanitary storage and disposal of waste.

(E) If an incinerator is provided, it shall be separated as required in subparagraph (24)(C)2.T. of this rule.

*AUTHORITY: sections 192.005.2 and 197.080, RSMo 1986. * This rule was previously filed as 13 CSR 50-20.031 and 19 CSR 10-20.031. Original rule filed June 2, 1982, effective Nov. 11, 1982. Amended: Filed June 14, 1988, effective Oct. 13, 1988.*

**Original authority: 192.005.2, RSMo 1985 and 107.080, RSMo 1953.*

19 CSR 30-20.040 Definitions Relating to Long-Term Care Units in Hospitals

PURPOSE: This rule defines terminology used throughout 19 CSR 30-20.050 and 19 CSR 30-20.060.

(1) Ambulatory resident. An ambulatory resident shall mean a resident who is capable mentally and physically of negotiating a normal path to safety using assistive devices or aides when necessary, including ascent and descent of stairs.

(2) Competency evaluation program. The completion of the state training agency's formerly required one hundred thirty-five (135)-hour nursing assistant training course before January 1, 1989 and the successful completion of the state training agency's special four (4)-hour retraining program, which includes taking and passing the final examination to the nursing assistant training course as required in 13 CSR 15-13.010(7)(J); a challenge to the final examination of the nursing assistant training course in accordance with 13 CSR 15-13.010(7)(B)5.; or enrolling in and successfully completing the one hundred seventy-five (175)-hour nursing assistant training course as described in 13 CSR 15-13.010(6).

(3) 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.

(4) Licensed nurse. A practical nurse or a registered nurse.

(5) 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, an intermediate care unit or a residential care unit.

(6) Nonambulatory resident or bed patient. A nonambulatory resident or bed patient is a person who is confined to bed eighty percent (80%) of the time or who is unable to reposition him/herself in a chair unaided.

(7) Nursing assistant. An employee, including a nurse aid or orderly, who is assigned to a long-term care unit of a hospital to provide or assist in providing direct resident health care services under the supervision of a nurse licensed under the Nursing Practice Act, Chapter 335, RSMo.



to have these possessions reasonably protected;

(I) The patient has the right to accept medical care or to refuse it to the extent permitted by law and to be informed of the medical consequences of refusal. The patient has the right to appoint a surrogate to make health care decisions on his/her behalf to the extent permitted by law;

(J) The patient, responsible party or designee has the right to participate in treatment decisions and the care planning process;

(K) The patient has the right to be informed of the hospital's patient grievance policies and procedures, including who to contact and how; and

(L) The patient has the right to file a formal or informal verbal or written grievance and to expect a prompt resolution of the grievance, including a timely written notice of the resolution. The grievance may be made by a patient or the patient's representative. Any patient service or care issue that cannot be resolved promptly by staff present will be considered a grievance for purposes of this requirement. The written notice of the resolution should include information on the steps taken on behalf of the patient to investigate the grievance, the results of the investigation, and the date the investigation was completed. If the corrective action is still being evaluated, the hospital's response should state that the hospital is still working to resolve the grievance and the hospital will follow-up with another written response when the investigation is complete or within a specified time frame.

*AUTHORITY: sections 192.006 and 197.080, RSMo 2000. * This rule previously filed as 19 CSR 30-20.021(2)(B)17. Original rule filed June 27, 2007, effective Feb. 29, 2008.*

**Original authority: 192.006, RSMo 1993, amended 1995 and 197.080, RSMo 1953, amended 1993, 1995.*

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. 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 podiatry 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 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 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. 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, revocation, curtailment, suspension, revocation, or other modification of clinical privileges of a member of the medical staff.

(6) Any applicant for medical staff membership who is denied membership 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 whose membership or privi-

leges 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 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.

(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 non-compliance.

(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.

AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154, RSMo Supp. 2007. This rule previously filed as 19 CSR 30-20.021(2)(C). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.088 Central Services

PURPOSE: This rule specifies the manner in which central services shall be organized and integrated in a hospital.

(1) Central services shall be organized and integrated with patient care services in the hospital.

(2) The director of central services shall be qualified by education, training and experience in aseptic technique, principles of sterilization and disinfection, and distribution of medical/surgical supplies. The director shall be responsible to an administrative officer or a qualified designee.

(3) Sufficient supervisory and support staff shall be assigned as related to the scope of services provided.

(4) Sufficient space and equipment shall be provided for the safe and efficient operation of the services as determined by the scope of hospital services delivered.

(5) Policies and procedures shall define the activities and locations of all services provided, be reviewed and kept current per hospital policy, and be readily available to staff. Sterilization and disinfection standards of practice shall be established, kept current, and approved by the hospital's infection control committee.

(6) Written procedures shall specify how items stored in central services can be obtained when central services is considered closed.

(7) Reprocessed, reusable packaged item(s) shall be identified as to content, show evidence of sterilization, and be labeled indicating the sterilizer used and the load/cycle number. A policy on the shelf life of a packaged sterile item shall be established in accordance with acceptable standards of sterilization and dependent on the quality of the packaging

material, storage conditions, and the amount of handling of the item.

(8) Central services shall maintain documentation from the manufacturer that packaging material utilized for reprocessing is appropriate for this use. Expiration dates shall comply with the packaging material utilized.

(9) Sterile medical-surgical packaged items shall be handled only as necessary and stored in vermin-free areas where controlled ventilation, temperature and humidity are maintained. The integrity of sterile items shall be maintained throughout reprocessing, storage, distribution, and transportation.

(10) Preventive maintenance of equipment shall not be performed less frequently than as recommended by the manufacturer or as specified by hospital policy. Records shall be maintained as specified by hospital policy. Records shall include documentation that items have been processed in accordance with the manufacturer's recommendations to obtain pathogenic microbial kill.

(11) Hospital policy shall be developed based on the manufacturer's recommendations to eliminate the hazards from processed items to patients and staff.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(3)(A). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.090 Food and Nutrition Services

PURPOSE: This rule specifies the manner in which food and nutrition services shall be organized and integrated in a hospital.

(1) The hospital shall have an employee or contracted individual designated who—

(A) Serves as director of food and nutrition services;

(B) Is responsible for the daily management of the food and nutrition services;

(C) Is qualified by education, training, and experience in food service management and nutrition through an approved course for certification by the Dietary Managers Association or registration by the Commission on Dietetic Registration of the Academy of Nutrition and

Dietetics, or an associate degree in dietetics or food systems management; and

(D) Has documented evidence of annual continuing education.

(2) When the director is not a qualified dietitian, a qualified dietitian shall be employed on a part-time or consultant basis. The dietitian shall make visits to the facility to assist in meeting the nutritional needs of the patients and the scope of services offered.

(3) The director shall ensure that a qualified dietitian provides high quality nutritional care to patients in accordance with recognized dietary practices as evidenced by the following:

(A) Continuing liaison with the administration, medical staff, and nursing staff; and

(B) Evaluation and approval of the planned written menus including regular and routine modified diets for nutritional adequacy.

(4) The director or designee shall ensure the following:

(A) Patient and family counseling and diet instructions;

(B) Nutritional screening within twenty-four (24) hours of inpatient admission to identify patients at nutritional risk. The hospital shall develop criteria to use in conducting the nutritional screening and staff who conduct the screening shall be trained to use the criteria;

(C) Comprehensive nutritional assessments within seventy-two (72) hours after screens on patients at nutritional risk, including height, weight, and pertinent laboratory tests;

(D) Documentation of pertinent information in patient's records, as appropriate; and

(E) Participation in committee activities concerned with nutritional care.

(5) The director or designee shall be responsible for—

(A) Representing the food and nutrition service in interdepartmental meetings;

(B) Recommending the quantity and quality of food purchased;

(C) Participating in the selection, orientation, training, scheduling, and supervision of food and nutrition personnel;

(D) Developing a procedure to provide appropriate substitutions or a selective menu for patients with food preferences and/or intolerances;

(E) Monitoring adherence to the written planned menu; and

(F) Scheduling food and nutrition services meetings.



(6) When the qualified dietitian serves as a consultant, written reports shall be submitted to and approved by the chief executive officer or designee concerning the services provided.

(7) The director shall have the authority to implement written policies and procedures governing food and nutrition services and shall have the responsibility for evaluating and monitoring to ensure they are followed. The policies and procedures shall include processes to ensure appropriate nutritional care and clinically-indicated nutritional interventions are provided during the admission. Nutritional care planning shall be a component of the overall discharge plan when clinically indicated. Policies and procedures shall be reviewed and kept current per hospital policy and readily available to staff.

(8) Food and nutrition services shall be staffed with a sufficient number of qualified personnel.

(9) Menus shall be planned, written, and followed to meet the nutritional needs of the patients as determined by the recommended dietary allowances (RDA) of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, or as modified by physician's order.

(10) Diets shall be prescribed in accordance with the diet manual approved by the qualified dietitian and the medical staff. The diet manual shall be available to all medical, nursing, and food service personnel.

(11) At least three (3) meals or their equivalent shall be offered with supplementary snacks as necessary.

(12) Food and nutrition records shall be maintained which include: food specifications and purchase orders; meal count; standardized recipes; menu plans; nutritional evaluation of menus; and minutes of departmental and in service education meetings.

(13) The food and nutrition services shall comply with 19 CSR 20-1.025 Sanitation of Food Establishments.

(14) When there is a contract to provide food and nutrition services to a hospital, the hospital is responsible for assuring that contractual services comply with rules concerning food and nutrition services in hospitals.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19*

CSR 30-20.021(3)(B). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.092 Emergency Services in Hospitals

PURPOSE: This rule establishes the requirements for emergency services in a hospital.

(1) Each hospital providing general services to the community shall provide an easily accessible emergency area which shall be equipped and staffed to ensure that ill or injured persons can be promptly assessed and treated or transferred to a facility capable of providing needed specialized services. In multiple-hospital communities where written agreements have been developed among the hospitals in accordance with an established community-based hospital emergency plan, individual hospitals may not be required by the Department of Health to provide a fully equipped emergency service.

(2) A hospital shall have a written hospital emergency transfer policy and written transfer agreements with one (1) or more hospitals within its service area which provide services not available at the transferring hospital. Transfer agreements shall be established which reflect the usual and customary referral practice of the transferring hospital, but are not intended to cover all contingencies.

(3) Hospital emergency services shall be under the medical direction of a qualified staff physician who is board-certified or board-admissible in emergency medicine and maintains a knowledge of current ACLS and ATLS standards or a physician who is experienced in the care of critically ill and injured patients and maintains current verification in ACLS and ATLS. In pediatric hospitals, PALS shall be substituted for ACLS. With the explicit advanced approval of the Department of Health, a hospital may contract with a qualified consultant physician to meet this requirement.

(A) That physician shall be responsible for implementing rules of the medical staff relating to patient safety and privileges and to the quality and scope of emergency services.

(B) A qualified registered nurse shall supervise and evaluate the nursing and patient care provided in the emergency area by nursing and ancillary personnel. Supervision may

be by direct observation of staff or, at a minimum, the nurse shall be immediately available in the institution.

(C) Any person assigned to the emergency services department administering medications shall be a licensed physician, registered nurse, EMT-paramedic or appropriately licensed or certified allied health practitioner and shall administer medications only within his/her scope of practice except for students who are participating in a training program to become physicians, nurses, emergency medical technician-paramedics who may be allowed to administer medication under the supervision of their instructors as a part of their training. Trained individuals from the respiratory therapy department may be allowed to administer aerosol medications when a certified respiratory therapy assistant is not available.

(4) Any hospital which provides emergency services and does not maintain a physician in-house twenty-four (24) hours a day for emergency care shall have a call roster which lists the name of the physician who is on call and available for emergency care and the dates and times of coverage. A physician who is on call and available for emergency care shall respond in a manner which is reasonable and appropriate to the patient's condition after being summoned by the hospital.

(5) Any hospital with surgical services that also provide emergency surgical services shall have a general surgical call roster which lists the name of the general surgeon who is on call for emergency surgical cases, and the dates and times of coverage. The surgeon who is on call for emergency surgical cases shall arrive at the hospital within thirty (30) minutes of being summoned. Patients arriving at a hospital that does not provide emergency surgical services and are found upon examination to require emergency surgery shall be immediately transferred to a hospital with the necessary services.

(6) All patients admitted to the emergency service shall be assessed prior to discharge by a physician or registered professional nurse.

(7) If discharged from the emergency department, other than to the inpatient setting, the patient or responsible person shall be given written instructions for care and an oral explanation of those instructions. Documentation of these instructions shall be entered on the emergency service medical record.

(8) There shall be a quality improvement program for the emergency service which



includes, but is not limited to, the collection and analysis of data to assist in identification of health service problems, and a mechanism for implementation and monitoring appropriate actions. The quality improvement program shall include the periodic evaluation of at least the following: length of time each patient is in the emergency room, appropriateness of transfers, physician response time, provision for written instructions, timeliness of diagnostic studies, appropriateness of treatment rendered, and mortality.

(9) Written policies shall be adopted to assure that notification procedures are implemented concerning the significant exposure of pre-hospital emergency personnel to communicable diseases as required in 19 CSR 30-40.047.

(10) The emergency service medical record shall contain patient identification, time and method of arrival, history, physical findings, treatment and disposition and shall be authenticated by the physician. These records, including an ambulance report when applicable, shall be filed under supervision of the medical records department.

(11) There shall be a mechanism for the review and evaluation on a regular basis of the quality and appropriateness of emergency services.

(12) A hospital shall have a written plan that details the hospital's criteria and process for diversion. The plan must be reviewed and approved by the Missouri Department of Health prior to being implemented by the hospital. A hospital may continue to operate under a plan in existence prior to the effective date of this section while awaiting approval of its plan by the department.

(A) The diversion plan shall:

1. Identify the individuals by title who are authorized by the hospital to implement the diversion plan;

2. Define the process by which the decision to divert will be made;

3. Specify that the hospital will not implement the diversion plan until the authorized individual has reviewed and documented the hospital's ability to obtain additional staff, open existing beds that may have been closed or take any other actions that might prevent a diversion from occurring;

4. Include that all ambulance services within a defined service area will be notified of the intent to implement the diversion plan upon the actual implementation. Ambulances that have made contact with the hospital before the hospital has declared itself to be on

diversion shall not be redirected to other hospitals. In areas served by a real time, electronic reporting system, notification through such system shall meet the requirements of this provision so long as such system is available to all EMS agencies and hospitals in the defined service area;

5. Include procedures for assessment, stabilization and transportation of patients in the event that services, including but not limited to, ICU beds or surgical suites become unavailable or overburdened. These procedures must also include the evaluation of services and resources of the facility that can still be provided to patients even with the implementation of the diversion plan;

6. Include procedures for implementation of a resource diversion in the event that specialized services are overburdened or temporarily unavailable; and

7. Include that all other acute care hospitals within a defined service area will be notified upon the actual implementation of the diversion plan. For defined service areas with more than two (2) hospitals, if more than one-half (1/2) of the hospitals implement their diversion plans, no hospital will be considered on diversion. For a defined service area with two (2) hospitals, if both hospitals implement their diversion plans, neither will be considered on diversion. Participation in a real time, electronic reporting system shall meet the notification requirements of this section. If a hospital participates in an approved community wide plan, the community wide plan may set the requirement for the number of hospitals to remain open.

(B) Each incident of diversion plan implementation must be reviewed by the hospital's existing quality assurance committee. Minutes of these review meetings must be made available to the Missouri Department of Health and Senior Services upon request.

(C) The hospital shall assure compliance with screening, treatment and transfer requirements as required by the Emergency Medical Treatment and Active Labor Act (EMTALA).

(D) A hospital or its designee shall report to the department, by phone or electronically, upon actual implementation of the diversion plan. This implementation report shall contain the time the plan will be implemented. The hospital or its designee shall report to the department, by phone or electronically, within eight (8) hours of the termination of the diversion. This termination report shall contain the time the diversion plan was implemented, the reason for the diversion, the name of the individual who made the determination to implement the diversion plan, the time the diversion status was terminated, and

the name of the individual who made the determination to terminate the diversion. In areas served by real time, electronic reporting system, reporting through such system shall meet the requirements of this provision so long as such system generates reports as required by the department.

(E) Each hospital shall implement a triage system within its emergency department. The triage methodology shall continue to apply during periods when the hospital diversion plan is implemented.

(F) Any hospital that has a written approved policy, which states that the hospital will not go on diversion or resource diversion, except as defined in the hospital's disaster plan in the event of a disaster, is exempt from the requirements of 19 CSR 30-20.021(3)(C)12.

(G) If a hospital chooses to participate in a community wide plan, the requirements of number of hospitals to remain open, defined service areas, as well as community notification may be addressed within the community plan. Community plans must be approved by the department. Community plans must include that each hospital has a policy addressing diversion and the criteria used by each hospital to determine the necessity of implementing a diversion plan. Participation in a community plan does not exempt a hospital of the requirement to notify the department of a diversion plan implementation.

AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154, RSMo Supp. 2007. This rule previously filed as 19 CSR 30-20.021(3)(C). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.094 Medical Records

PURPOSE: This rule establishes minimum requirements for medical records kept in hospitals.

(1) The director of the medical record services shall be appointed by the chief executive officer or chief operating officer. This director may be a registered health information administrator, a health information technician, or an individual with demonstrated competence and knowledge of medical record department activities supervised by a qualified consultant who is a registered health information administrator or health information technician.



(2) All patient care documentation shall be entered in the patient's medical record promptly. Such documentation shall be legible, dated, timed, authenticated, and recorded.

(3) All orders, including verbal orders, shall be dated, timed, and authenticated according to hospital policy, but no later than thirty (30) days, by the ordering practitioner or another practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy and shall be kept in the patient's medical record. Authentication shall consist of written signatures, initials, or computer-generated signature codes.

(4) The hospital shall have a written policy that includes abbreviations, acronyms, symbols, and dose designations approved by the medical staff for use in the hospitals and those prohibited from use in the hospital. The prohibited list applies to all orders, preprinted forms and medication related documentation.

(5) The medical record of each patient shall be maintained in order to justify admission and continued hospitalization, support the diagnosis, describe the patient's progress and response to medications and services, and to facilitate rapid retrieval and utilization by authorized personnel.

(6) Medical records are the property of the hospital and shall not be removed from the hospital except by court order, subpoena, or for off-site storage approved by the governing body.

(7) Written consent of the patient or the patient's legal representative is required for access to or release of information, copies or excerpts from the medical record to persons not otherwise authorized to receive this information.

(8) Patient records shall be considered complete when the required contents are assembled and authenticated. Hospital policy shall define circumstances in which incomplete medical records may be closed.

(9) All medical records shall include, as appropriate:

(A) A medical history and physical examination completed and authenticated no more than thirty (30) days before or twenty-four (24) hours after admissions or registration, but prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies. The medical history and physical examination shall be placed in the patient's medical

record within twenty-four (24) hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies.

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within thirty (30) days before admission or registration. Documentation of the updated examination shall be placed in the patient's medical record within twenty-four (24) hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies;

(C) Admitting diagnosis;

(D) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

(E) Documentation of complications, healthcare-associated infections, and unfavorable reactions to drugs and anesthesia;

(F) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state law if applicable, requiring written patient consent;

(G) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, laboratory reports, vital signs, and other information necessary to monitor the patient's condition;

(H) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care; and

(I) Final diagnosis with completion of medical records within thirty (30) days following discharge.

(10) A certificate of live birth shall be prepared for each child born alive and shall be forwarded to the local registrar, or as otherwise directed by the state registrar within five (5) days after the date of delivery. If the physician or other person in attendance does not certify to the facts of birth within five (5) days after the birth, the person in charge of the institution shall complete and sign the certificate.

(11) When a dead fetus is delivered in an institution, the person in charge of the institution or his/her designated representative shall prepare and, within seven (7) days after delivery, file a report of fetal death with the local registrar or as otherwise directed by the state registrar.

(12) Medical records of deceased patients shall contain the date and time of death,

autopsy permit, if granted, disposition of the body, by whom received and when.

(13) The State Anatomical Board shall be notified of an unclaimed dead body. A record of this notification shall be maintained.

(14) The patient's medical records shall be maintained to safeguard against loss, defacement, unauthorized access, and tampering and to prevent damage from fire and water. Medical records shall be preserved in a permanent file in the original, on microfilm, or other electronic media. Patients' medical records shall be retained for a minimum of ten (10) years, except that a minor shall have his/her record retained until his/her twentieth birthday, whichever occurs later. Preservation of medical records may be extended by the hospital for clinical, educational, statistical, or administrative purposes.

(15) There shall be a process for the review and evaluation on a regular basis of the quality of medical record services.

(16) Should the hospital cease to be licensed, arrangements for disposition of the patient medical records shall be made with nearby hospitals, the patient's physician, or a reliable storage company. Notification of the disposition is to be provided to the Department of Health and Senior Services.

*AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. * This rule previously filed as 19 CSR 30-20.021(3)(D). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.096 Nursing Services

PURPOSE: This rule establishes the requirements for nursing services in a hospital.

(1) The nursing service shall be integrated and identified within the total hospital organizational structure.

(2) The nursing service shall have a written organizational structure that indicates lines of authority, accountability, and communication.

(3) The organization of the nursing service shall conform with the variety of patient care



services offered and the range of nursing care activities.

(4) Nursing policies and standards of practice describing patient care shall be in writing and be kept current and readily available to staff.

(5) Policies shall provide for the collaboration of nursing personnel with members of the medical staff and other health care disciplines regarding patient care issues.

(6) Nursing service policies shall establish an appropriate committee structure to oversee and assist in the provision of quality nursing care. The purpose and function of each committee shall be defined and a record of its activities shall be maintained.

(7) Policies shall make provision for nursing personnel to be participants of hospital committees concerned with patient care activities.

(8) Policies shall be developed regarding the use of overtime. The policies shall be based on the following standards:

(A) Overtime shall not be mandated for any licensed nursing personnel except when an unexpected nurse staffing shortage arises that involves a substantial risk to patient safety and a reasonable effort has been made to secure safe staffing. Reasonable efforts undertaken shall be documented by the hospital. Reasonable efforts shall include pursuing all of the following:

1. Reassigning on-duty staff;
2. Seeking volunteers to work extra time from all available qualified nursing staff who are presently working;
3. Contacting qualified off-duty employees who have made themselves available to work extra time, per diem staff, float pool, and flex team nurses; and
4. Seeking personnel from a contracted temporary agency or agencies when such staffing is permitted by law or an applicable collective bargaining agreement and when the employer regularly uses the contracted temporary agency or agencies;

(B) The prohibition of mandatory overtime does not apply to overtime work that occurs because of an unforeseeable emergency or when a hospital and a subsection of nurses commit, in writing, to a set, predetermined staffing schedule or prescheduled on-call time. An unforeseeable emergency is defined as a period of unusual, unpredictable, or unforeseeable circumstances such as, but not limited to, an act of terrorism, a disease outbreak, adverse weather conditions, or natural disasters which impact patient care and which pre-

vent replacement staff from reporting for duty;

(C) Other than overtime permitted under subsections (8)(A) and (B), the facility is prohibited from requiring a nurse to work additional consecutive hours beyond the nurse's predetermined schedule of hours when doing so may, in the nurse's judgment, jeopardize patient safety and from taking action against a nurse on the grounds that a nurse failed to work the additional hours or when a nurse declines to work additional consecutive hours;

(D) Nurses required to work more than twelve (12) consecutive hours under subsections (8)(A) or (B) shall be provided the option to have at least ten (10) consecutive hours of uninterrupted off-duty time immediately following the worked time; and

(E) The nursing service shall maintain and make available upon request to the department a list of qualified nurses, nurse registries, and per diem nurses that may be called upon to provide replacement staff in the event of sickness, vacations, vacancies, disasters, and other absences of direct care nursing staff.

(9) The nursing service shall be administered and directed by a qualified registered professional nurse with appropriate education, experience, and demonstrated ability in nursing practice and management.

(10) The nursing service administrator shall be responsible to the chief executive officer or chief operating officer.

(11) The nursing service administrator shall be a full-time employee and shall have the authority and be accountable for assuring the provision of quality nursing care for those patient areas delineated in the organizational structure.

(12) The nursing service administrator shall participate in the formulation of hospital policies and the development of long-range plans relating to patient care.

(13) The nursing service administrator, or designee, shall represent nursing at all appropriate meetings of the medical staff and governing board of the hospital.

(14) The nursing service administrator shall be accountable for the selection, promotion, and termination of all nursing personnel under the authority of nursing service.

(15) A qualified registered professional nurse shall be designated and authorized to act in

the absence of the nursing service administrator.

(16) Nursing personnel shall hold a valid and current license in accordance with sections 335.011–335.096, RSMo.

(17) There shall be a job description for each classification of nursing personnel which delineates the specific qualifications, licensure, certification, authority, responsibilities, functions, and performance standards for that classification. Job descriptions shall be reviewed per hospital policy and revised as necessary to reflect current job requirements.

(18) There shall be scheduled annual evaluations of job performance for all classifications of nursing personnel.

(19) All nursing personnel shall be oriented to the hospital, nursing services, their position classification, the use of overtime, and the nursing service regulation 19 CSR 30-20.096. The orientation shall be of sufficient length and content to prepare nursing personnel for their specified duties and responsibilities. Competency shall be validated and documented prior to assuming independent performance in actual patient situations.

(20) Nursing personnel meetings shall be conducted at intervals necessary for leadership and to communicate management information. Separate meetings for the various job classifications of personnel may be conducted. Minutes of all meetings shall be maintained and reflect attendance, scope of discussion, and action(s) taken. The minutes shall be filed according to hospital policy.

(21) By January 15 of each year, every hospital shall develop, implement, and submit to the Department of Health and Senior Services, a written or electronic copy of the hospital-wide staffing plan for nursing services. Every hospital shall have a policy that requires the input on the staffing plan from direct care nursing staff from within the hospital.

(22) The hospital-wide staffing plan for nursing services shall:

(A) Include the number, skill mix, and qualifications of direct care nursing staff needed for each unit of the hospital;

(B) Be based on the expected nursing care required by the unit population and individual needs of each patient. The expected unit population and individual nursing care needs of each patient shall be the major consideration in determining the number and skill mix of direct care nursing staff needed;



(C) Identify relevant factors in each hospital unit including, but not limited to, the number of patients in a unit; intensity of care required; skill and experience of care givers including registered nurses, licensed practical nurses, ancillary personnel, and other members of the patient care team consistent with the level of authority and responsibility delegated under state licensure; admission, discharge, and transfers; nonpatient care duties; geography of a unit; and the availability of technological support;

(D) Provide for documentation of the actual staffing plan; and

(E) Nurses included in the staffing plan count shall spend a minimum of seventy-five percent (75%) of their time providing direct patient care.

(23) Every hospital shall establish nursing sensitive indicators and monitor outcomes of these indicators to evaluate the adequacy of the hospital-wide staffing plan for nursing services. At least one (1) of each of the following three (3) types of outcomes shall be used to evaluate the adequacy of the staffing plan:

(A) Patient outcomes such as patient falls, adverse drug events, injuries to patients, skin breakdown, infection rates, length of stay, or patient readmissions;

(B) Operational outcomes such as work-related injury or illness, vacancy and turnover rates, nursing care hours per patient day, on-call use, or overtime rates; and

(C) Validated patient complaints related to staffing levels.

(24) The hospital shall, in consultation with its direct care nursing staff, monitor and evaluate the hospital-wide staffing plan and nursing sensitive outcomes for effectiveness on a continual basis and revise the plan annually and as necessary.

(25) Each facility shall develop and utilize a methodology which ensures it is staffed with sufficient numbers and skill mix of appropriately qualified direct care nursing staff in each unit to meet the unit population and individualized care needs of the patients. Each unit shall document actual staffing and patient census during every shift.

(26) At a minimum, there shall be a sufficient number of registered professional nurses on duty at all times to provide patient care requiring the judgment and skills of a registered professional nurse and to supervise the activities of all nursing personnel.

(27) There shall be sufficient licensed and ancillary nursing personnel on duty on each

nursing unit to meet the needs of each patient in accordance with accepted standards of nursing practice.

(28) Each nursing unit shall post in a visible location on the nursing unit or make available to the patient(s) or patient's authorized representative a copy of the unit's hospital-wide staffing plan for nursing services and documentation of actual daily staffing levels.

(29) Patient care assignments shall be consistent with the qualifications of the nursing personnel and the identified patient needs.

(30) A registered professional nurse shall assess the patient's needs for nursing care in all settings where nursing care is provided. A nursing assessment shall be completed within twenty-four (24) hours of admission as an inpatient. The registered professional nurse may be assisted in the process by other qualified nursing staff members.

(31) Evidence of planning the patient's care, education, and discharge needs shall be addressed, kept current, and appropriately documented in the medical records.

(32) The necessary types and quantities of supplies and equipment shall be available to meet the current needs of each patient. Reference materials pertinent to patient care shall be readily accessible.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(3)(E). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Oct. 22, 2008, effective June 30, 2009. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.097 Safe Patient Handling and Movement in Hospitals

PURPOSE: This rule specifies the requirements for safe patient handling and movement practices in a hospital.

(1) There shall be an active multidisciplinary committee responsible for implementing and monitoring the safe patient handling and movement program. At least one-half (1/2) of the members of the committee shall be front-line non-managerial employees who are involved in patient care handling activities.

(2) This program shall include:

(A) A safe patient handling policy for all shifts that will achieve elimination of manual lifting, transferring, and repositioning of all or most of a patient's weight, except in emergency, life-threatening, or otherwise exceptional circumstances;

(B) A patient-handling hazard assessment that considers such variables as patient-handling tasks, types of nursing units, patient populations, and the physical environment of patient care areas;

(C) A process which assesses patient's needs for safe patient handling and movement;

(D) Educational materials for patients and their families to help orient them to the hospital's safe patient handling program;

(E) An annual evaluation of the program utilizing measurable outcome measures including but not limited to employee and patient injuries, lost work days, and workers' compensation claims; and

(F) Evidence of changes based on the program evaluation.

(3) All employees involved in patient care handling activities are to be trained and demonstrate competence on safe patient handling policies, equipment, and devices before implementation, annually, and as changes are made to the program.

AUTHORITY: section 197.080, RSMo 2000. Original rule filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 197.080, RSMo 1953, amended 1993, 1995.*

19 CSR 30-20.098 Pathology and Medical Laboratory Services

PURPOSE: This rule establishes the requirements for pathology and medical laboratory services in a hospital.

(1) Provision shall be made, either on the premises or by contract with a reference laboratory, for the prompt performance of adequate examinations in the fields of hematology, clinical chemistry, urinalysis, microbiology, immunology, anatomic pathology, cytology and immunohematology.

(2) The medical director of the pathology and medical laboratory services shall be a physician who is a member of the medical staff and appointed by the governing body. If the director is not a pathologist, a pathologist shall be retained on a part-time basis as a consultant on-site. Consultation shall be provided no less than monthly. A written report



Batterymarch Park, Quincy, MA 02169. This rule does not incorporate any subsequent amendments or additions.

(6) Fire-retardant protective coatings shall be applied to paneling and other materials at intervals as necessary to maintain the required flame-retardant properties.

(7) All draperies, curtains, and cubicle curtains shall be inherently flame-retardant or treated and maintained to retard flame.

(8) A written fire safety and evacuation plan shall be available to all personnel. The plan shall provide for the protection of all persons in the event of fire and for their evacuation to areas of refuge in or outside the building when necessary. All employees shall be periodically instructed and kept informed respecting their duties under the plan.

(9) Fire drills shall be held at least quarterly for each shift and shall include the simulated use of fire alarm signals and simulation of emergency fire conditions. The movement of patients is not required.

AUTHORITY: section 192.006, RSMo 2000, and section 197.080, RSMo Supp. 2013.* This rule previously filed as 19 CSR 30-20.021(3)(K). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.

*Original authority: 192.006, RSMo 1993, amended 1995 and 197.080, RSMo 1953, amended 1993, 1995.

19 CSR 30-20.110 Orientation and Continuing Education

PURPOSE: This rule specifies the requirements for orientation and continuing education programs in hospitals.

(1) There shall be an orientation and continuing education program for the development and improvement of necessary skills and knowledge of the facility personnel.

(2) The orientation program shall be of the scope and duration necessary to effectively prepare personnel new to a unit for their assigned duties and responsibilities based on job descriptions. Temporary personnel shall have documented evidence of hospital and unit specific orientation prior to providing direct patient care.

(3) Educational programs shall be conducted using internal or external resources and shall be planned and documented. Documentation

on the topic, presenter, date/time of presentation, and the program attendance shall be available.

(4) Educational resources and suitable references shall be identified and supplied as needed for the staff of each department or unit that provides direct patient care.

(5) The orientation and continuing education program shall participate in the performance improvement process and shall provide evaluation opportunities appropriate to its goals and objectives.

(6) The orientation and continuing education program shall include, as appropriate for the job, but not be limited to:

(A) Problems and needs of specific age groups, chronically ill, acutely ill, and disabled patients;

(B) Prevention, cause, effect, transmission, and control of infections including universal precautions;

(C) Reporting employee infections and injuries;

(D) Customer service, teamwork, and communication skills;

(E) Fire prevention, safety, and accident prevention;

(F) Patient rights including dignity, handling grievances, Health Insurance Portability and Privacy Act of 1996 (HIPAA), and privacy issues;

(G) Licensed nursing personnel training on basic cardiac life support and choking prevention and intervention;

(H) Prevention, identification, minimization, and reporting of patient and employee safety risks;

(I) Prevention, detection, intervention, and reporting abuse and neglect;

(J) Responsibilities during internal and external disasters;

(K) Tobacco-free policy; and

(L) Any other educational need identified through the quality improvement activities and those generated by advances made in health care science and technology.

(7) Competency of all employees shall be evaluated annually based on job description and necessary job skills and knowledge.

AUTHORITY: section 192.006, RSMo 2000, and section 197.080, RSMo Supp. 2013.* This rule previously filed as 19 CSR 30-20.021(3)(L). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed June 6, 2013, effective Jan. 30, 2014.

*Original authority: 192.006, RSMo 1993, amended 1995 and 197.080, RSMo 1953, amended 1993, 1995, 2013.

19 CSR 30-20.112 Quality Assessment and Performance Improvement Program

PURPOSE: This rule specifies the requirements for quality improvement programs in a hospital.

(1) The governing body shall ensure the development and implementation of an effective, ongoing, systematic hospital-wide, patient-oriented quality assessment and performance improvement plan.

(2) This plan shall be designed to measure, assess, and improve the quality of patient care as evidenced by patient health outcomes or improvement in processes, or both.

(3) The performance improvement plan shall be written and shall include:

(A) Description of the plan purpose, objectives, organizations, scope, authority, responsibility, and mechanisms of a planned systematic, organization-wide approach to designing, measuring, assessing, and improving performance;

(B) Assurance of collaborative participation from appropriate departments and services, both clinical and nonclinical, including those services provided directly and under contract;

(C) Provision for assessment and coordination of quality improvement activities through an established oversight team that meets on an established periodic basis;

(D) Assurance of ongoing communication, reporting, and documentation of patient-care issues and quality improvement activities and their effectiveness to the governing body and medical staff at least quarterly; and

(E) Development of an annual assessment of the effectiveness of the plan.

(4) At a minimum, the plan shall include:

(A) Organization-wide design, measurement, assessment, and improvement of patient care and organizational functions;

(B) Review of care that includes outcomes of care provided by the medical and nursing staff and by other health care practitioners employed or contracted by the hospital;

(C) Measurements of quality of care which are outcome- or process-based, specific to the hospital, and to identified needs and expectations of the patients and staff;

(D) Review on a continuing basis of the processes that affect a large percentage of patients, that place patients at risk or that have caused or are likely to cause quality problems; and



(E) The performance improvement plan shall be designed to review activity, actions initiated, and reassessments. Documentation shall be maintained on these activities.

*AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. * This rule previously filed as 19 CSR 30-20.021(3)(M). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed June 6, 2013, effective Jan. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995, 2013; and 197.154, RSMo 2004.*

19 CSR 30-20.114 Environmental Waste Management and Support Services

PURPOSE: This rule specifies the requirements for environmental and support services provided by a hospital.

(1) Each hospital shall have an organized service which maintains a clean and safe environment.

(A) Housekeeping Services.

1. The housekeeping services shall have a director who is qualified by education, training, and experience in the principles of hospital housekeeping. This individual shall report to a designated administrative officer or his or her designee.

2. Approved written policies and procedures shall define and describe the scope of housekeeping services. These shall be reviewed in cooperation with the infection prevention control program, kept current per hospital policy, and be readily available to staff.

3. Adequate space for housekeeping services shall be provided.

4. There shall be sufficient trained personnel to meet the needs of housekeeping services.

5. All solid waste generated within the hospital shall be collected in appropriate containers for disposal.

6. There shall be a process for the review and evaluation on a regular basis of the quality of housekeeping services provided.

(B) Laundry and Linen Services.

1. The hospital shall have organized services which ensure that adequate supplies of clean linens are available. There shall be specific written procedures for the processing, distribution, and storage of linen. These shall be reviewed in cooperation with the infection control committee and kept current.

2. Soiled linen processing functions shall be physically separated from both clean linen storage and soiled linen holding areas. Only commercial laundry equipment shall be used to process hospital linen.

3. Clean linen shall be stored and distributed to the point of use in a way that minimizes microbial contamination from surface contact or airborne particles.

4. Soiled linen shall be collected at the point of use and transported to the soiled linen holding room in a manner that minimizes microbial dissemination into the environment.

5. If a commercial laundry service is used, verification shall be provided to assure the hospital that the processing and handling of linen complies with paragraphs (1)(B)1.-4. of this rule and by following manufacturer recommendations.

6. There shall be a process for the review and evaluation on a regular basis of the quality of laundry and linen services provided.

(C) Infectious Waste Management

1. The director of this program shall be qualified by education, training, and experience in the principles of infectious waste management.

2. Every hospital shall write an infectious waste management plan with an annual review identifying infectious waste generated on-site, the scope of the infectious waste program, and policies and procedures to implement the infectious waste program. The plan shall include at least the following:

A. Contact information for responsible individuals; organizational chart; schematic(s) of waste disposal routes; definition of those wastes handled by the system; department and individual responsibilities; hospital policies and procedures for waste identification, segregation, containment, transport, treatment, and disposal; emergency and contingency procedures; training and educational procedures; and appendices (rules and other applicable institutional policy statements).

B. Any hospital exempt from infectious waste processing facility permit requirements of 10 CSR 80-7.010 and that accepts infectious waste from off-site shall include in its plan requirements for storage, processing, and record keeping of this waste and the cleanup of potential spills in the unloading area.

C. Manufacturers' specifications for temperature, residence time, and control devices for any infectious waste processing devices shall be included in the plan.

3. A trained operator shall operate the equipment during any infectious waste treatment procedures.

4. Infectious waste shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leakproof containers or plastic bags appropriate for the characteristics of the infectious waste. Containers for infectious waste shall be identified with the universal

biological hazard symbol. All packaging shall maintain its integrity during storage and transport. Infectious waste shall not be placed in a gravity waste disposal chute.

5. Pending disposal, infectious waste shall be stored, separated from other wastes, in a limited-access enclosure posted with the biological hazard symbol. This enclosure shall afford protection from vermin, be a dry area, and be provided with an impervious floor with a perimeter curb. The floor shall slope to a drain connected to the sanitary sewage system or collection device. If infectious waste is compacted, the mechanical device shall contain the fluids and aerosols and shall not release aerosols or fluids when opened and the container is removed. Provisions for waste stored seventy-two (72) hours or more shall be separately addressed in the infectious waste management plan to include proper storage, handling, and disposal by commercial vendors when utilized.

6. Hospital infectious waste treated on site shall be rendered innocuous, using one (1) of the following methods:

A. Sterilization of the waste in an autoclave is permitted, provided that the unit is operated in accordance with the manufacturer's recommendations and that the autoclave's effectiveness is verified at least weekly with a biological spore assay containing *Bacillus Stearothermophilus*. If the autoclave is used for other functions, the infectious waste management plan will develop specific guidelines for its use;

B. Decontamination of the infectious waste by other technologies in a manner acceptable to the Department of Health and Senior Services shall be permitted;

C. Bulk blood, suctioned fluids, excretions, and secretions may be carefully poured down a drain connected to a sanitary sewer; or

D. Infectious waste rendered innocuous by the methods in subparagraphs (1)(C)6.A. or B. of this rule shall be disposed of in accordance with the requirements of 10 CSR 80-7.010.

7. An infectious waste treatment program shall include records of biological spore assay tests if required by treatment methods and the approximate amount of waste disinfected per hour measured by weight per load. The program director shall maintain records demonstrating the proper operation of the disinfection equipment.

8. All infectious waste when transported off the premises of the hospital shall be packaged and transported as provided in sections 260.200-260.207, RSMo.

9. Any hospital which accepts infectious waste from small quantity generators as defined by 10 CSR 80-7.010 or from other Missouri hospitals—in quantities exceeding



fifty percent (50%) of the total poundage of infectious waste generated on-site at the hospital—shall notify the Department of Natural Resources and comply with permitting requirements of sections 260.200–260.207, RSMo. The weight of infectious waste generated on-site shall be calculated by multiplying one and five-tenths (1.5) pounds per day times the number of beds complying with Department of Health and Senior Services standards for hospital licensure. Infectious waste generated off-site may be accepted by a hospital only if packaged according to 10 CSR 80-7.010(2)(A)–(D).

(D) Medication Waste Management.

1. Disposal of unwanted medications and medication waste shall be identified in the following categories: general, controlled substances, radiologic, infectious, and hazardous. Medication waste shall include materials contaminated with such medications.

A. Specific waste streams shall be identified for each category including storage container type, storage prior to disposal, and final disposition.

B. Medications shall be returned to the pharmacy for disposal except—

(I) Single doses that may be disposed of by medication staff at the time of administration;

(II) Doses that are an infectious hazard; and

(III) Radiopharmaceuticals.

C. Medications shall be disposed of according to the Missouri Department of Natural Resources, the United States Food and Drug Administration, and the United States Environmental Protection Agency.

D. Disposal of controlled substances shall be according to 19 CSR 30-1.078.

E. Unused radiopharmaceuticals shall be returned to the supplier or held and disposed of according to Nuclear Regulatory Commission guidelines.

F. Disposal of hazardous medications including, but not limited to, antineoplastic medications shall be handled as follows:

(I) Personnel who handle hazardous medications and/or medication waste shall be trained regarding collection, transportation, containment, segregation, manifest, and disposal; and

(II) Waste shall be contained and segregated from other waste in leak proof containers clearly labeled with a statement such as CAUTION: HAZARDOUS CHEMICAL WASTE and held in a secure place until disposed.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(5)(A), (C), and (D). Original rule filed June 27, 2007, effective Feb. 29,*

2008. Amended: Filed June 6, 2013, effective Jan. 30, 2014.

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995, 2013; and 197.154, RSMo 2004.*

19 CSR 30-20.116 Infection Prevention and Control

PURPOSE: This rule specifies the requirements for infection prevention and control practices in a hospital.

(1) There shall be an active multidisciplinary infection prevention and control committee responsible for implementing and monitoring the infection prevention and control program for patients and staff. The committee shall include, but not be limited to, the infection control officer, a member of the medical staff, registered professional nursing staff, quality improvement staff, and administration. This program shall include measures for preventing, identifying, reporting, and investigating healthcare-associated infections and shall establish procedures for collecting data, participating in root cause analysis, and implementing corrective actions as relevant to infection prevention and control. These measures and procedures shall be applied throughout the hospital.

(2) The infection prevention and control committee shall conduct an ongoing review and analysis of healthcare-associated infections (HAI) data and risk factors. Priorities and goals related to active surveillance, monitoring, reporting, and preventing the acquisition and the acquisition and transmission of potentially infectious agents will be established based on risks identified.

(3) Hospitals shall implement written policies and procedures outlining infection prevention and control measures. These measures shall include, but are not limited to, a hospital-wide hand hygiene program. This program must comply with current national standards endorsed by Centers for Disease Control and Prevention (CDC) or World Health Organization guidelines. At a minimum, the program shall require every healthcare worker to properly wash or sanitize his or her hands immediately before and immediately after having direct contact with a patient. Procedures shall include, at a minimum, requirements for the facility's infection prevention and control program to conduct surveillance of personnel in accordance with section 197.150, RSMo. Surveillance procedures may also include monitoring the employees' and medical staff's use

of hand hygiene products.

(4) All areas of the hospital shall have a process for reporting patient and employee infections. A process for monitoring compliance with infection prevention and control policies and procedures shall be coordinated with the infection prevention and control committee.

(5) Infection prevention and control committee meetings shall be held at least quarterly. Minutes shall be retained per hospital policy.

(6) There shall be a process for the review and evaluation on a regular basis of the quality and scope of the infection prevention and control program.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080, 197.150, and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(5)(B). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; 197.150, RSMo 2004; and 197.154, RSMo 2004.*

19 CSR 30-20.118 Outpatient Services in Hospitals

PURPOSE: This rule specifies the requirements for outpatient services provided by a hospital.

(1) Outpatient services, if provided through an organized department of the hospital, shall be under the medical direction of qualified physician member(s) of the medical staff and appointed by the governing body. The physician(s) shall be responsible for implementing rules of the medical staff governing the quality and scope of outpatient services provided.

(2) Outpatient services shall be integrated with other hospital services as required to meet the needs of the patient.

(3) Nursing personnel assigned to outpatient services shall be under the supervision of a qualified registered professional nurse with relevant education, experience, and demonstrated current competency.

(4) Approved written policies and procedures shall describe the scope of outpatient care provided. Policies and procedures shall be reviewed, kept current per hospital policy, and made readily available to staff.



(5) Outpatient services shall be staffed by personnel qualified by education, training, and experience to provide safe patient care.

(6) Patient's medical records shall reflect outpatient care and treatment provided. These records shall be filed and maintained under supervision of the medical records department.

(7) There shall be a process for the review and evaluation on a regular basis of the quality and appropriateness of outpatient services provided.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(4)(A). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed June 6, 2013, effective Jan. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995, 2013; and 197.154, RSMo 2004.*

19 CSR 30-20.120 Anesthesia Services in Hospitals

PURPOSE: This rule specifies the requirements for anesthesia services in a hospital.

(1) Anesthesia services, if provided, shall be under the medical direction of a qualified physician member of the medical staff and appointed by the governing body. This physician shall be responsible for implementing the rules of the medical staff governing the quality and scope of anesthesia care provided.

(2) Approved written policies and procedures shall include: patient and employee safety, pre- and post-anesthesia evaluation, care of equipment, storage of anesthesia agents and the administration of anesthesia.

(3) Anesthesia shall be administered only by qualified anesthesiologists, physicians or dentists trained in anesthesia, certified nurse anesthetists or supervised students in an approved educational program.

(4) An anesthesia record documenting the care given shall be a permanent part of the patient's medical record.

(5) The pre-anesthesia patient evaluation shall be accomplished by a physician and documented within forty-eight (48) hours before surgery and shall include the history and physical examination; anesthetic, drug and

allergy history; essential laboratory data; and other diagnostic test results to establish potential anesthetic risks. These procedures may be waived in the event of a life threatening emergency, provided the surgeon so certifies on the patient medical record.

(6) A post-anesthesia evaluation shall be documented in the patient's medical record within twenty-four (24) hours after surgery.

(7) The use of flammable anesthetic agents shall be limited to those areas of the hospital which comply with all applicable requirements of the *Standard for Inhalation Anesthetics 1980* published by the National Fire Protection Association.

(8) Prior to surgery, the patient's medical record shall contain evidence that the patient has been advised regarding the surgical procedure(s) contemplated, the type of anesthesia to be administered and the risks involved with each. Evidence that informed consent has been given shall become a part of the patient's medical record.

(9) There shall be a mechanism for the review and evaluation on a regular basis of the quality and scope of anesthesia services.

AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154, RSMo Supp. 2007. This rule previously filed as 19 CSR 30-20.021(4)(B). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.122 Home-Care Services in Hospitals

(Rescinded January 30, 2014)

AUTHORITY: sections 192.006 and 197.080, RSMo 2000, and section 197.154, RSMo Supp. 2007. This rule previously filed as 19 CSR 30-20.021(4)(C). Original rule filed June 27, 2007, effective Feb. 29, 2008. Rescinded: Filed June 6, 2013, effective Jan. 30, 2014.

19 CSR 30-20.124 Medical Services

PURPOSE: This rule specifies the requirements for medical services in a hospital.

(1) Medical services, if provided, shall be under the medical direction of a qualified physician member of the medical staff and appointed by the governing body as chief of

the medical services. This director shall be responsible for implementing the rules of the medical staff governing medical privileges and the quality of medical care provided.

(2) Medical services shall be responsible for the medical care of all patients except those under the care of physicians or other services as defined in the medical staff or governing body bylaws.

(3) The activities of medical services shall be integrated with other services in the hospital.

(4) There shall be a process for the review and evaluation on a regular basis of the quality and appropriateness of medical services provided.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(4)(D). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed June 6, 2013, effective Jan. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995, 2013; and 197.154, RSMo 2004.*

19 CSR 30-20.125 Unlicensed Assistive Personnel Training Program

PURPOSE: This rule requires hospitals to have a personnel training policy that requires unlicensed health care personnel who provide direct patient care under the delegation and supervision of a registered nurse to complete the Unlicensed Assistive Personnel (UAP) Training Program, which shall be used to prepare individuals for employment in hospitals. This program shall be designed to teach the knowledge and skills that will qualify students to perform uncomplicated nursing procedures and assist in direct patient care.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.



(1) Hospitals may only employ or contract with a staffing agency for unlicensed assistive personnel (UAP) in accordance with this rule.

(2) The hospital training policy for UAPs shall include the following minimum standards:

(A) The curriculum of the UAP Program shall consist of a standard plan of instruction to include:

1. A minimum of seventy-five (75) hours of classroom instruction;

2. Computer or paper-based learning modules that provide documentation of completion may be substituted for up to sixty (60) hours of classroom time;

3. Comparable certified medical assistant training from an accredited medical assistant program may be substituted for up to fifty (50) hours of classroom time of comparable subject matter;

4. A minimum of one hundred (100) hours of clinical practicum; and

5. Curriculum content of the program shall include procedures and instructions on basic patient care skills including, but not limited to, the areas of:

A. The Role of the UAP (ethics, law, team member communication, observation, reporting, documentation, medical terminology);

B. Patient/Client Rights (Health Insurance Portability and Accountability Act (HIPAA), privacy, confidentiality, advanced directives, abuse and neglect, age specific care, cultural diversity, pain management, restraint-free care, end-of-life care, death and dying, do not resuscitate (DNR) orders, post-mortem care);

C. Vital Signs;

D. Basic Human Needs (age specific cognitive/psychological/social needs, activities of daily living, ambulation, positioning, personal care, elimination and toileting, nutrition, hydration, feeding, bed making);

E. Infection Control (universal precautions, blood-borne pathogens, safe needle devices, aseptic technique, hand washing, gloving, isolation);

F. Skin Care (wound care, pressure ulcers and prevention); and

G. Safety (cardiopulmonary resuscitation (CPR), allergies, fall prevention, environmental safety issues, fire/electrical, hazardous materials transportation safety information (HAZMAT), emergency procedures, body mechanics).

(B) The clinical practicum of one hundred (100) hours shall start after the student has enrolled and started the course curriculum.

(C) Skill validation and knowledge verification is to be used to determine student competence.

(D) Annual in-service training also shall occur as required by 19 CSR 30-20.110.

(3) Hospitals shall not be required to meet the UAP training requirements if an employee demonstrates competency in the content areas required by this rule; in the duties specific to their job and the patient population assigned and—

(A) Is enrolled in a professional or practical nursing education program and has or will complete within ninety (90) days a fundamentals of nursing course; or

(B) Was a professional nursing or practical nursing licensure candidate who failed to pass the state licensure examinations in the past three (3) years; or

(C) Is certified as a nursing assistant as defined in section 198.082, RSMo; or

(D) Has documentation of current registration as a certified nursing assistant in another state that meets the requirements listed in 42 CFR 483.151 and 483.152 (April 2012) which are incorporated by reference in this rule and are published by the U.S. Government Printing Office, 710 North Capitol Street, NW, Washington, DC 20401. This rule does not incorporate any subsequent amendments or additions; or

(E) Has documented experience as a nurse assistant, emergency medical technician, or surgical technician in the past three (3) years; or

(F) Has proof of completion of UAP training program in Missouri or another state which meets the requirements of this rule within the last three (3) years; or

(G) Has completed a professional or licensed practical nursing program outside the United States and is awaiting the licensure examination in this country.

(4) The hospital training policy for UAPs shall meet the following faculty qualifications and responsibilities:

(A) A registered professional nurse shall be designated as the course coordinator and shall be responsible for all aspects of the course, and must supervise all classroom and clinical instruction;

(B) Instructors shall hold a current license or temporary permit to practice as a registered professional nurse in Missouri or in another Nurse Licensure Compact state and have a minimum of two (2) years of nursing experience in an acute care, long-term care, or ambulatory surgery facility within the prior five (5) years, or an experience as a clinical faculty member in a nursing program within the prior five (5) years. An instructor's nursing license shall not be under current disciplinary action;

(C) A clinical supervisor's or preceptor's nursing license shall not be under current disciplinary action; and

(D) UAPs who have satisfied the training requirements of this rule and Licensed Practical Nurses may assist with the clinical practicum under the direction of the course coordinator.

(5) A hospital or ambulatory surgical center that provides training for UAPs shall meet the following training site requirements:

(A) Provide designated space sufficient to accommodate the classroom teaching portion of the course or have a written agreement with another acute care hospital, an area vocational-technical school, a high school offering a health service occupation program, a community college, or a provider agency to provide the classroom portion of the course;

(B) Provide on-the-job clinical practicum or have a written agreement with one (1) or more hospitals or ambulatory surgical centers in their vicinity to do so;

(C) Assess and review the program and outcomes of any training provided by another facility to ensure that all of the requirements of this rule have been met;

(D) Maintain, either electronically or on paper records of course completion and competency for a minimum of three (3) years. Records shall be signed and dated by the course coordinator and each of the instructors and clinical supervisors verifying classroom time, clinical time, and competency for each student; and

(E) Provide a signed copy of the course completion and competency record to the student, that includes the elements in subsection (5)(D) of this rule.

(6) The UAP training shall be completed within ninety (90) days of employment for any individual who is hired as a UAP. A UAP shall not work in direct patient care, except as part of their supervised practicum, until the entire UAP training requirements have been met.

AUTHORITY: section 197.287, RSMo Supp. 2013. Original rule filed Jan. 31, 2008, effective Sept. 30, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.*

**Original authority: 197.287, RSMo 2000.*

19 CSR 30-20.126 Obstetrical and Newborn Services in Hospitals

PURPOSE: This rule specifies the requirements for obstetrical and newborn services in a hospital.



(1) Obstetrical services, if provided, shall be under the medical direction of a qualified physician member of the medical staff and appointed by the governing body. This physician shall be responsible for implementing the rules of the medical staff governing obstetrical privileges, quality of obstetrical care and patient safety.

(2) Obstetrical services shall be supervised by a qualified registered professional nurse with relevant education, experience and demonstrated current competency.

(3) The obstetrical nursing supervisor shall have the authority to implement and enforce hospital policies and procedures governing obstetrical services and shall have the responsibility for evaluating the competency of nursing personnel assigned to obstetrical services.

(4) Facilities for obstetrical services shall be designed to prevent unauthorized traffic.

(5) Undelivered patients receiving intravenous oxytocin shall be under continuous observation by trained personnel. Induction or augmentation of labor with oxytocin may be initiated only after a qualified physician has evaluated the patient, determined that induction or augmentation is beneficial to the mother, fetus, or both, recorded the indication and established the plan of management. The physician initiating these procedures shall be readily accessible to manage complications that arise during infusion and a physician who has privileges to perform Caesarean deliveries shall be in consultation and readily accessible in order to manage any complications that require surgical intervention.

(6) There shall be provision for isolation of infants with known or suspected infections or communicable diseases. Policies and procedures regarding isolation shall be integrated with the hospital infection control program.

(7) Each newborn shall be identified by an acceptable method which includes the name, date and time of birth, the infant's sex and the mother's hospital number.

(8) A delivery room record shall be maintained.

(9) A nursery shall be provided for care of the newborn.

(10) Hospitals with an obstetrical service shall have at least one (1) premature-care incubator by an independent testing laboratory.

(11) All cases of acute infectious conjunctivitis (*Ophthalmia neonatorum*) shall be reported immediately to the individual(s) responsible for the infection control program and to the local or district health department in accordance with section 210.080, RSMo.

(12) All cases of epidemic diarrhea of the newborn shall be reported immediately to the individual(s) responsible for the infection control program and the local or district health department.

(13) Resuscitation, suction, oxygen, monitoring and newborn temperature control equipment shall be available for the care of newborn. Supplies for the proper care of newborn shall be available.

(14) An incubator or bassinet with controlled temperature shall be available for each delivery room and for transport to the nursery.

(15) Space shall be provided for the preparation or the handling and storage of formula. Separate refrigeration shall be provided for formula.

(16) Eye care of newborn shall be in accordance with section 210.070, RSMo.

(17) Written policies and procedures shall be established to provide safe transport of infants within the hospital or to another health-care facility.

(18) Written policies and procedures governing special care programs shall be approved by the medical staff and governing body.

(19) There shall be a mechanism for the review and evaluation on a regular basis of the quality of obstetrical and newborn services provided.

AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154, RSMo Supp. 2007. This rule previously filed as 19 CSR 30-20.021(4)(E). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.128 Pediatric Services in Hospitals

PURPOSE: This rule specifies the requirements for pediatric services in a hospital.

(1) The pediatric unit, if provided, shall be under the medical direction of a qualified

physician member of the medical staff and appointed by the governing body. This physician shall be responsible for implementing the rules of the medical staff governing the quality and scope of pediatric services.

(2) The pediatric unit shall be supervised by a qualified registered professional nurse with relevant education, experience and demonstrated current competency.

(3) The pediatric supervisor shall have the authority to implement and enforce hospital policies and procedures governing pediatric services and shall have the responsibility for evaluating the competency of nursing personnel assigned to pediatric services.

(4) The pediatric unit shall be designed for specific needs of children and located apart from adult patients and the newborn.

(5) The pediatric unit shall have at least one (1) room suitable for isolation.

(6) Supplies and equipment required for emergencies shall be readily available in the pediatric unit.

(7) There shall be a mechanism for the review and evaluation on a regular basis of the quality and appropriateness of pediatric services provided.

AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154, RSMo Supp. 2007. This rule previously filed as 19 CSR 30-20.021(4)(F). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.130 Post-Anesthesia Recovery Services in Hospitals

PURPOSE: This rule specifies the requirements for post-anesthesia recovery services in a hospital.

(1) Post-anesthesia recovery services, if provided, shall be under the medical direction of a qualified physician member of the medical staff and appointed by the governing body. This director shall be responsible for implementing the rules of the medical staff governing post-anesthesia recovery services.

(2) A qualified registered professional nurse shall direct and evaluate the nursing care provided by post-anesthesia recovery services.



record.

(8) Space and equipment shall be provided to meet the needs of rehabilitation services. Space, supplies and equipment shall be maintained to ensure patient safety.

(9) There shall be a mechanism for the review and evaluation on a regular basis of the quality and appropriateness of rehabilitation services provided.

AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154, RSMo Supp. 2007. This rule previously filed as 19 CSR 30-20.021(4)(I). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.136 Respiratory Care Services

PURPOSE: This rule specifies the requirements for respiratory care services in a hospital.

(1) Respiratory care services, if provided, shall be under the medical direction of a qualified physician member of the medical staff and appointed by the governing body. The director shall be responsible for implementing rules of the medical staff governing the quality and scope of respiratory care services.

(2) Respiratory care services shall be integrated within the total hospital organizational plan.

(3) Respiratory care services shall be under the direction of a licensed respiratory care practitioner or a registered professional nurse with relevant education and experience. When the director is not a licensed respiratory care practitioner, a licensed respiratory care practitioner shall be employed on a part-time consultant basis.

(4) Therapy shall be administered in accordance with the orders of a qualified and licensed practitioner and shall be documented in the patient's medical record.

(5) Respiratory care services shall be provided by qualified personnel as specified by the medical staff.

(6) Approved written policies and procedures which define and describe the scope and conduct of respiratory care shall be reviewed and

kept current per hospital policy and readily available to staff.

(7) Personnel administering respiratory therapy services shall evaluate and reevaluate the therapy administered and this shall be documented in the patient's medical record.

(8) Space and equipment shall be provided to meet the needs of respiratory care services. Space, supplies, and equipment shall be maintained to ensure patient safety.

(9) There shall be a process for the review and evaluation on a regular basis of the quality and appropriateness of respiratory care services provided.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(4)(J). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.138 Specialized Inpatient Care Services

PURPOSE: This rule specifies the requirements for special patient care services in a hospital.

(1) Each specialized inpatient care service, if provided, shall be under the medical direction of a qualified physician who is a member of the medical staff and appointed by the governing body. This shall not prohibit a qualified physician from being the medical director of more than one (1) specialized inpatient care service area.

(2) Patient care in each specialized inpatient care service area shall be integrated with the other nursing services and supervised by a qualified registered professional nurse with relevant education, experience, and demonstrated current competency.

(3) Each specialized inpatient care service area shall have written policies and procedures that are reviewed and kept current per hospital policy and are readily available to staff.

(4) Qualifications of personnel assigned to each specialized inpatient care service area shall be delineated in writing.

(5) A multi-disciplinary committee, chaired by the director, shall develop protocols for patient care in each specialized inpatient care service area. This committee shall meet at least quarterly and minutes shall be kept and filed on a confidential basis.

(6) There shall be a process for the review and evaluation on a regular basis of the quality and appropriateness of care provided in each specialized inpatient care service area.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(4)(K). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.140 Surgical Services

PURPOSE: This rule specifies the requirements for surgical services in a hospital.

(1) Surgical services, if provided, shall be under the medical direction of a qualified physician member of the medical staff and appointed by the governing body. This physician shall be responsible for implementing rules of the medical staff governing the quality and scope of surgical services.

(2) Approved written policies and procedures shall define and describe the scope and conduct of surgical services. These shall be kept current per hospital policy and are readily available to staff.

(3) The surgical suite shall be directed by a qualified registered professional nurse with relevant education and experience. This director shall have the authority to implement hospital policies and procedures for the surgical suite and shall have the responsibility for evaluating all nursing personnel assigned to the surgical suite.

(4) A qualified registered professional nurse with relevant education, experience, and competency shall be assigned circulating duties for surgical procedures performed.

(5) Accepted standards of patient care, sterility, and aseptic techniques shall be maintained.



(6) Prior to surgery, except in the case of emergencies, the patient’s medical record shall contain evidence of informed consent.

(7) A medical history and physical examination must be completed and documented no more than thirty (30) days before or twenty-four (24) hours after admission or registration but prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies. An updated examination of the patient, including any changes in the patient’s condition, must be completed and documented within twenty-four (24) hours after admission or registration when the medical history and physical examination are completed within thirty (30) days before admission or registration, except in the case of emergencies. The medical history and physical examination must be placed in the patient’s medical record within twenty-four (24) hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies.

(8) An operating room record documenting the patient care provided shall become a part of the patient’s medical record. The record shall contain at least the name and hospital identification number of the patient; date and times of the surgery; name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks; pre-operative and post-operative diagnosis; name of the specific surgical procedure(s) performed; type of anesthesia administered; any complications; description of techniques, findings, and tissues removed or altered; any prosthetic devices, grafts, tissues, transplants, or devices implanted; and the verification of countable materials.

(9) There shall be a process for the review and evaluation on a regular basis of the quality and appropriateness of surgical services.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(4)(L). Original rule filed June 27, 2007, effective Feb. 29, 2008. Amended: Filed Dec. 31, 2013, effective Aug. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

19 CSR 30-20.142 Variance Requests

PURPOSE: This rule specifies the manner through which hospitals may request a vari-

ance from 19 CSR 30-20.001 through 19 CSR 30-20.140.

(1) Requests for variance from the requirements of 19 CSR 30-20.015 through 19 CSR 30-20.140 shall be in writing to the Department of Health and Senior Services. Department determinations in response to variance requests shall be in writing and both requests and determinations shall be made a part of the Department of Health and Senior Services permanent records for the facility.

(A) Requests shall contain at a minimum—

1. The section number and text of the rule in question;
2. Specific reasons why compliance with the rule would impose an undue hardship on the operator, including an estimate of any additional cost which might be involved;
3. An explanation of the extenuating factors which may be relevant;
4. A complete description of the individual characteristics of the facility or patients or any other factors which would fulfill the intent of the rule in question to safeguard the health, safety, and the welfare of the patient, staff, or public if the variance from the requirement is granted; and
5. A length of time the variance is being requested.

(2) The department’s written determination shall identify a variance expiration date, if approved. The facility may re-apply for a variance up to ninety (90) days prior to the expiration of a department-approved variance.

(3) Any facility granted a variance by the department shall inform the department in writing if the conditions warranting the variance change. This written notification to the department shall be made within thirty (30) days of the change affecting the variance. The department may revoke the granted variance if the changes in conditions detrimentally impact the health, safety, and the welfare of the patient, staff, or public, as determined by the department.

(4) All previously approved variances shall be submitted at the time of annual licensure renewal.

AUTHORITY: section 192.006, RSMo 2000, and sections 197.080 and 197.154, RSMo Supp. 2013. This rule previously filed as 19 CSR 30-20.021(1) and (1)(A). Original rule filed on June 27, 2007, effective Feb. 29, 2008. Amended: Filed June 6, 2013, effective Jan. 30, 2014.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995, 2013; and 197.154, RSMo 2004.*

SELECTED DHSS RULES

2.25.16 Revised 4.6.16

The first 5 rules—definitions, medical staff, emergency services, anesthesia and ob/newborn—contain proposed new language. I apologize that the bold text for new language did not come through. Language to be deleted is in brackets [xxx]. Highlighted text for emphasis only.

The rest of the rules are current language. Most have been recently updated.

All rules include only selected sections.

19 CSR 30-20.011 Definitions Relating to Hospitals

(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.

(7) [(5)] **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.]

(Deleted) [(6) **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.]

(10) **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.

(Deleted) [(12) **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.]

(Deleted) [(13) **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.]

(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.19 CSR 30-20.080

(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. (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.

(252) **Licensed practitioner**: Any individual who is licensed and qualified to practice a health care profession.

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

(40) **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.

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

(43) [(24)] **Pharmacist**—An individual who is [a graduate of a school or college of pharmacy and is] currently licensed to practice pharmacy in the State of Missouri.

(44) **Pharmacist Intern** – an individual who is currently licensed as a pharmacist intern in the State of Missouri.

(45) **Pharmacy technician**—an individual who is currently registered as a pharmacy technician in the State of Missouri.

(49) **Premises** – Buildings, floors and areas located on tracts of property which are adjacent to the hospital but for a common street or highway and its accompanying right-of-way may be included in the hospital's license if they meet subsection... (ADD SUBSECTION).

(63) **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.

19 CSR 30-20.030 Construction Standards

(3) General Design. Construction shall meet the **Guidelines for Design and Construction of Health Care Facilities, Facility Guidelines Institute (FGI), 2010 Edition**, except that all references to National Fire Protection Association (NFPA) included in the FGI shall refer to the NFPA 101, 2000 Edition. National Fire Protection Association (NFPA) 101 Life Safety Code, 2000 Edition, and all referenced NFPA publications shall apply to general design and construction. The Guidelines for Design and Construction of Health Care Facilities, Facility Guidelines Institute (FGI), 2010 Edition, are incorporated by reference in this rule and available from the American Society for Healthcare Engineering of the American Hospital Association (ASHE), 155 North Wacker Drive, Chicago, IL 60606, 800-242-2626, www.fgiguidelines.org. This rule does not incorporate any subsequent amendments or additions. The National Fire Protection Association (NFPA) 101 Life Safety Code, 2000 Edition, is incorporated by reference in this rule and is available at, 1 Batterymarch Park, Quincy, MA 02269, 617-770-3000, www.nfpa.org. This rule does not incorporate any subsequent amendments or additions.

19 CSR 30-20.086 Medical Staff [in Hospitals].

PURPOSE: This amendment provides clarification on certain aspects related to medical staff within hospitals and **adds a specific comment concerning the appointment of nonphysician practitioners to the medical staff.**

(2) Medical staff membership shall be **limited to physicians, dentists, psychologists and podiatrists.** **Non-physician practitioners may be appointed to medical staff if such practice is consistent with the scope of their professional license.** 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 podiatry schooling, postgraduate training or certification. [, if the schooling] The school or postgraduate training program for a physician [was] shall be accredited by the American Medical Association or the American Osteopathic Association[.]; for a dentist, [was] shall be accredited by the American Dental Association['s Commission on Dental Accreditation.]; for a psychologist, [was] shall be accredited [with accordance to Chapter 337, RSMo] by the American Psychological Association; and for a podiatrist, [was] shall be accredited by the American Podiatric Medical Association. Each application for staff membership shall be considered on an individual basis with objective criteria applied [equally] uniformly to each applicant.

(4) [Each physician, dentist, psychologist or podiatrist] Applicants requesting staff membership shall submit a complete written and signed 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, a signed statement that they will observe hospital policies and procedures, and other information as required by the medical staff bylaws or policies.

(5) Written criteria shall be developed for privileges extended to each member of the staff. A formal [mechanism] process 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] process 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 who is denied membership or whose completed application is not acted upon in ninety (90) calendar days [of] from the completion of credentialing verification [of credentials data] or a medical staff member 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] 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.

(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; standing committees; committee functions; frequency of meetings; 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] related to 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] process shall be established for [monthly] interim 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 shall determine retention guidelines and guidelines for release of minutes not containing peer review materials in accordance with the hospital records retention policy.

(13) The medical staff shall establish in its bylaws or rules criteria for the content of [patients'] medical records, provisions for their timely completion and disciplinary action for noncompliance, consistent with applicable state and federal law.

(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 for emergency care within a reasonable period of time [for emergency service] that is appropriate to the patient's condition.

(15) With approval of the governing body, the medical staff may rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site entity physicians and practitioners providing telemedicine services, if the hospital's governing body ensures, through its written agreement with the distant-site entity, that all of the following provisions are met: (A) The distant-site entity

providing the telemedicine services is a Medicareparticipating hospital. (B) The individual distant-site entity physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site entity physician's or practitioner's privileges at the distant-site hospital. (C) The individual distant-site entity physician or practitioner holds a license issued or recognized by the State of Missouri. (D) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site entity physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site entity physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site entity physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site entity physician or practitioner.

19 CSR 30 – 20.092 Emergency Services.

(This subsection deleted)

[(C) Any person assigned to the emergency services department administering medications shall be a licensed physician, registered nurse, EMT-paramedic or appropriately licensed or certified allied health practitioner and shall administer medications only within his/her scope of practice except for students who are participating in a training program to become physicians, nurses, emergency medical technician-paramedics who may be allowed to administer medication under the supervision of their instructors as a part of their training. Trained individuals from the respiratory therapy department may be allowed to administer aerosol medications when a certified respiratory therapy assistant is not available.]

19 CSR 30-20.120 Anesthesia Services [in Hospitals].

(3) Anesthesia shall be administered only by a practitioner qualified and authorized under Missouri law to administer anesthesia. This includes qualified anesthesiologists[,] and physicians licensed pursuant to Chapter 334, RSMo; [or] dentists [trained in] authorized to administer anesthesia[,]under Chapter 332, RSMo; certified registered nurse anesthetists; anesthesiologist assistants; [or] supervised students in [an] approved educational programs; or other practitioners authorized by Missouri law. Anesthesia administered by certified registered nurse anesthetists, anesthesia assistants, or others shall be supervised as required by Missouri laws applicable to their scope of practice.

(4) [An anesthesia records documenting the care given shall be a permanent part of the patient's medical record.

(5)] The pre-anesthesia patient evaluation shall be accomplished by an anesthesiologist, a physician licensed pursuant to Chapter 334, RSMo, or dentist authorized under Chapter 332, RSMo, to administer anesthesia, or certified registered nurse anesthetist under the supervision of an anesthesiologist or other licensed physician, as required by section 334.104, RSMo, and documented in the patient's medical record within forty-eight (48) hours before surgery and shall include the history and physical examination; anesthetic, drug and allergy history; essential laboratory data; and other diagnostic test results to establish potential anesthetic risks. These

procedures may be waived in the event of a life threatening emergency provided the surgeon so certifies on the patient medical record.

(5) Prior to administration of anesthesia, except in the case of emergencies, the patient's medical record shall contain evidence of **informed consent**.

(6) Prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies, a medical **history and physical examination** shall be completed and documented in the patient's medical record no more than thirty (30) days before or twentyfour (24) hours after admission or registration.

(7) Except in the case of emergencies, an updated examination of the patient, including any changes in the patient's condition, shall be completed and documented in the patient's medical record within twenty-four (24) hours after admission or registration when the medical history and physical examination are completed within thirty (30) days before admission or registration.

(8) An **anesthesia record** documenting the anesthesia care given shall be a permanent part of the patient's medical record. The record shall contain at a minimum the name and hospital identification number of the patient; name of practitioner who administered anesthesia; and as applicable, the name and profession of the supervising anesthesiologist or supervising physician or qualified dentist; name, dosage, route and time of administration of **drugs and anesthesia agents; intravenous fluids**; any blood or blood products used; oxygen flow rate; continuous recordings of patient status noting blood pressure, heart and respiration rate; and any complications or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment.

(9) Patients receiving **post-anesthesia recovery care** shall be closely observed by qualified personnel until each patient is stabilized for safe transfer. Written procedures for discharge from the post-anesthesia recovery service shall be approved by the medical staff.

[(6)] (10) A post-anesthesia evaluation shall be completed and documented in the patient's medical record [within twenty-four (24)] by qualified anesthesiologists, physicians licensed pursuant to Chapter 334, RSMo, or dentist authorized under Chapter 332, RSMo, to administer anesthesia, or certified registered nurse anesthetist under the supervision of an anesthesiologist or other licensed physician, as required by section 334.104, RSMo, no later than forty-eight (48) hours after surgery or a procedure requiring anesthesia services. The evaluation shall include respiratory function, including respiratory rate, airway patency, and oxygen saturation; cardiovascular function, including pulse rate and blood pressure; mental status; temperature; pain; nausea and vomiting; and postoperative hydration.

[(7)] (11) The use of **flammable anesthetic agents** shall be limited to those areas of the hospital which comply with all applicable requirements of the [Standard for Inhalation Anesthetics 1980 published by the National Fire Protection Association] **NFPA 99**, Standard for Health Care Facilities, 1999; and NFPA 101, Life Safety Code, 2000, which are incorporated by reference in this rule and are published by the National Fire Protection Association (NFPA), NFPA Headquarters, 1 Batterymarch Park, Quincy, MA 02169. This rule does not incorporate any subsequent amendments or additions. [(8) Prior to surgery, the patient's medical record shall contain evidence that the patient has been advised regarding the surgical procedure(s) contemplated, the type of anesthesia to be administered and the risks involved with each. Evidence that informed consent has been given shall become a part of the patient's medical record.

(9) (12) There shall be a [mechanism] process for the **review and evaluation** on a regular basis of the **quality and scope** of anesthesia services.

19 CSR 30 – 20.126 Obstetrical and Newborn Services [in Hospitals].

(5) Undelivered patients receiving intravenous oxytocin shall [be under continuous observation by trained personnel] have one-to-one (1:1) observation by a physician or a registered professional nurse competent in obstetrics. Induction or augmentation of labor with oxytocin may be initiated only after a qualified physician or a registered professional nurse in consultation with a qualified physician has evaluated the patient[,]; determined that induction or augmentation is indicated and beneficial to the mother, fetus, or both; recorded the indication and established the plan of management. The physician or certified nurse midwife initiating these procedures or the provider to whom care is transferred shall be readily accessible to manage complications that arise during infusion [and a]. A physician who has privileges to perform Caesarean deliveries shall be in consultation and readily accessible in order to manage any complications that require surgical intervention.

[(16)] (13) Eye care of newborn shall be in accordance with section 210.070, RSMo.

Prophylactic eyedrops at birth--report.

210.070. Every physician, midwife or nurse who shall be in attendance upon a newborn infant or its mother, shall drop into the eyes of such infant immediately after delivery, a prophylactic solution approved by the state department of health and senior services, and shall within forty-eight hours thereafter, report in writing to the board of health or county physician of the city, town or county where such birth occurs, his or her compliance with this section, stating the solution used by him or her.

THE FOLLOWING RULES ARE CURRENT AND NO CHANGES ARE PROPOSED

19 CSR 30-20.001 Anesthesiologist Assistants in Hospitals

PURPOSE: This rule allows the use of anesthesiologist assistants in hospitals.

(1) Anesthesiologist assistant—A person who meets each of the following conditions: (A) Has graduated from an anesthesiologist assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency; (B) Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants; (C) Has active certification by the National Commission on Certification of Anesthesiologist Assistants; (D) Is currently licensed as an anesthesiologist assistant in the state of Missouri; and (E) Provides health care services delegated by a licensed anesthesiologist.

(2) Notwithstanding any other rule in this chapter, anesthesia in hospitals shall be administered only by qualified anesthesiologists, physicians or dentists trained in anesthesia, certified nurse anesthetists, anesthesiologist assistants or supervised students in an approved educational program. Notwithstanding the provisions of sections 334.400 to 334.430, RSMo, or the rules of the Missouri State Board of Registration for the Healing Arts, the governing body of every hospital shall have full authority to limit the functions and activities that an anesthesiologist assistant performs in such hospital. Nothing in this section shall be construed to require any hospital to hire an anesthesiologist who is not already employed as a physician prior to August 28, 2003.

19 CSR 30-20.080 Governing Body of Hospitals

(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.

(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.

(18) Although independent licensed practitioners are not authorized membership to the medical staff, the governing body may include provisions within its bylaws to grant 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 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 at least every two (2) years. At a minimum, the criteria shall include documentation of a current license, relevant training and experience, and competency.

19 CSR 30-20.094 Medical Records

(2) All patient care documentation shall be entered in the patient's medical record promptly. Such documentation shall be legible, dated, timed, authenticated, and recorded.

(3) All orders, including verbal orders, shall be dated, timed, and authenticated according to hospital policy, but no later than thirty (30) days, by the ordering practitioner or another practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy and shall be kept in the patient's medical record. Authentication shall consist of written signatures, initials, or computer-generated signature codes.

(4) The hospital shall have a written policy that includes abbreviations, acronyms, symbols, and dose designations approved by the medical staff for use in the hospitals and those prohibited from use in the hospital. The prohibited list applies to all orders, preprinted forms and medication related documentation.

(5) The medical record of each patient shall be maintained in order to justify admission and continued hospitalization, support the diagnosis, describe the patient's progress and response to medications and services, and to facilitate rapid retrieval and utilization by authorized personnel.

(9) All medical records shall include, as appropriate: (A) A medical history and physical examination completed and authenticated no more than thirty (30) days before or twenty-four (24) hours after admissions or registration, but prior to surgery or a procedure requiring

anesthesia services, except in the case of emergencies. The medical history and physical examination shall be placed in the patient's medical record within twenty-four (24) hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies. (B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within thirty (30) days before admission or registration. Documentation of the updated examination shall be placed in the patient's medical record within twenty-four (24) hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, except in the case of emergencies; (C) Admitting diagnosis; (D) Results of all **consultative evaluations** of the patient and appropriate findings by clinical and other staff involved in the care of the patient; (E) Documentation of complications, healthcare-associated infections, and **unfavorable reactions to drugs and anesthesia**; (F) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state law if applicable, requiring written patient consent; (G) **All practitioners' orders**, nursing notes, reports of treatment, **medication records**, radiology, laboratory reports, vital signs, and other information necessary to monitor the patient's condition; (H) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care; and (I) Final diagnosis with completion of medical records within thirty (30) days following discharge.

(14) The patient's medical records shall be maintained to safeguard against loss, defacement, unauthorized access, and tampering and to prevent damage from fire and water. Medical records shall be preserved in a permanent file in the original, on microfilm, or other electronic media. **Patients' medical records shall be retained for a minimum of ten (10) years, except that a minor shall have his/her record retained until his/her twentieth birthday,** whichever occurs later. Preservation of medical records may be extended by the hospital for clinical, educational, statistical, or administrative purposes.

19 CSR 30-20.096 Nursing Services

(5) Policies shall provide for the **collaboration** of nursing personnel with members of the medical staff and **other health care disciplines** regarding patient care issues.

(7) Policies shall make provision for nursing personnel to be **participants of hospital committees concerned with patient care activities.**

(17) There shall be a job description for each classification of nursing personnel which delineates the specific qualifications, licensure, certification, authority, responsibilities, functions, and performance standards for that classification. Job descriptions shall be reviewed per hospital policy and revised as necessary to reflect current job requirements.

(23) Every hospital shall **establish nursing sensitive indicators and monitor outcomes** of these indicators to evaluate the adequacy of the hospital-wide staffing plan for nursing services. At least one (1) of each of the following three (3) types of outcomes shall be used to evaluate the adequacy of the staffing plan: (A) **Patient outcomes such as patient falls, adverse drug events, injuries to patients, skin breakdown, infection rates, length of stay, or patient readmissions;** (B) Operational outcomes such as workrelated injury or illness, vacancy and turnover rates, nursing care hours per patient day, oncall use, or overtime rates; and (C) Validated patient complaints related to staffing levels.

19 CSR 30-20.110 Orientation and Continuing Education

19 CSR 30-20.112 Quality Assessment and Performance Improvement Program

19 CSR 30-20.114 Environmental Waste Management and Support Services

(C) Infectious Waste Management 1. The director of this program shall be qualified by education, training, and experience in the principles of infectious waste management. 2. Every hospital shall write an infectious waste management plan with an annual review identifying infectious waste generated on-site, the scope of the infectious waste program, and policies and procedures to implement the infectious waste program. The plan shall include at least the following:

(D) Medication Waste Management. 1. Disposal of unwanted medications and medication waste shall be identified in the following categories: general, controlled substances, radiologic, infectious, and hazardous. Medication waste shall include materials contaminated with such medications. A. Specific waste streams shall be identified for each category including storage container type, storage prior to disposal, and final disposition. B. Medications shall be returned to the pharmacy for disposal except— (I) Single doses that may be disposed of by medication staff at the time of administration; (II) Doses that are an infectious hazard; and (III) Radiopharmaceuticals. C. Medications shall be disposed of according to the Missouri Department of Natural Resources, the United States Food and Drug Administration, and the United States Environmental Protection Agency. D. Disposal of controlled substances shall be according to 19 CSR 30-1.078. E. Unused radiopharmaceuticals shall be returned to the supplier or held and disposed of according to Nuclear Regulatory Commission guidelines. F. Disposal of hazardous medications including, but not limited to, antineoplastic medications shall be handled as follows: (I) Personnel who handle hazardous medications and/or medication waste shall be trained regarding collection, transportation, containment, segregation, manifest, and disposal; and (II) Waste shall be contained and segregated from other waste in leak proof containers clearly labeled with a statement such as CAUTION: HAZARDOUS CHEMICAL WASTE and held in a secure place until disposed.

(NOTE: need reference to USP 800?)

19 CSR 30-20.116 Infection Prevention and Control

(1) There shall be an active multidisciplinary infection prevention and control committee responsible for implementing and monitoring the infection prevention and control program for patients and staff. The committee shall include, but not be limited to, the infection control officer, a member of the medical staff, registered professional nursing staff, quality improvement staff, and administration. This program shall include measures for preventing, identifying, reporting, and investigating healthcare-associated infections and shall establish procedures for collecting data, participating in root cause analysis, and implementing corrective actions as relevant to infection prevention and control. These measures and procedures shall be applied throughout the hospital.

19 CSR 30-20.118 Outpatient Services in Hospitals

(1) Outpatient services, if provided through an organized department of the hospital, shall be under the medical direction of qualified physician member(s) of the medical staff and appointed

by the governing body. The physician(s) shall be responsible for implementing rules of the medical staff governing the quality and scope of outpatient services provided.

(4) Approved written policies and procedures shall describe the scope of outpatient care provided. Policies and procedures shall be reviewed, kept current per hospital policy, and made readily available to staff.

19 CSR 30-20.122 Home-Care Services in Hospitals (Rescinded January 30, 2014)

19 CSR 30-20.125 Unlicensed Assistive Personnel Training Program

PURPOSE: This rule requires hospitals to have a personnel training policy that requires unlicensed health care personnel who provide direct patient care under the delegation and supervision of a registered nurse to complete the Unlicensed Assistive Personnel (UAP) Training Program, which shall be used to prepare individuals for employment in hospitals. This program shall be designed to teach the knowledge and skills that will qualify students to perform uncomplicated nursing procedures and assist in direct patient care.

(1) Hospitals may only employ or contract with a staffing agency for unlicensed assistive personnel (UAP) in accordance with this rule.

(2) The hospital training policy for UAPs shall include the following minimum standards: (A) The curriculum of the UAP Program shall consist of a standard plan of instruction to include: 1. A minimum of seventy-five (75) hours of classroom instruction; 2. Computer or paper-based learning modules that provide documentation of completion may be substituted for up to sixty (60) hours of classroom time; 3. Comparable certified medical assistant training from an accredited medical assistant program may be substituted for up to fifty (50) hours of classroom time of comparable subject matter; 4. A minimum of one hundred (100) hours of clinical practicum; and 5. Curriculum content of the program shall include procedures and instructions on basic patient care skills including, but not limited to, the areas of: A. The Role of the UAP (ethics, law, team member communication, observation, reporting, documentation, medical terminology); B. Patient/Client Rights (Health Insurance Portability and Accountability Act (HIPAA), privacy, confidentiality, advanced directives, abuse and neglect, age specific care, cultural diversity, pain management, restraint-free care, end-of-life care, death and dying, do not resuscitate (DNR) orders, postmortem care); C. Vital Signs; D. Basic Human Needs (age specific cognitive/psychological/social needs, activities of daily living, ambulation, positioning, personal care, elimination and toileting, nutrition, hydration, feeding, bed making); E. Infection Control (universal precautions, blood-borne pathogens, safe needle devices, aseptic technique, hand washing, gloving, isolation); F. Skin Care (wound care, pressure ulcers and prevention); and G. Safety (cardiopulmonary resuscitation (CPR), allergies, fall prevention, environmental safety issues, fire/electrical, hazardous materials transportation safety information (HAZMAT), emergency procedures, body mechanics). (B) The clinical practicum of one hundred (100) hours shall start after the student has enrolled and started the course curriculum.

(C) Skill validation and knowledge verification is to be used to determine student competence.

(D) Annual in-service training also shall occur as required by 19 CSR 30-20.110.

(3) Hospitals shall not be required to meet the UAP training requirements if an employee demonstrates competency in the content areas required by this rule; in the duties specific to their job and the patient population assigned and— (A) Is enrolled in a professional or practical nursing education program and has or will complete within ninety (90) days a fundamentals of

nursing course; or (B) Was a professional nursing or practical nursing licensure candidate who failed to pass the state licensure examinations in the past three (3) years; or (C) Is certified as a nursing assistant as defined in section 198.082, RSMo; or (D) Has documentation of current registration as a certified nursing assistant in another state that meets the requirements listed in 42 CFR 483.151 and 483.152 (April 2012) which are incorporated by reference in this rule and are published by the U.S. Government Printing Office, 710 North Capitol Street, NW, Washington, DC 20401. This rule does not incorporate any subsequent amendments or additions; or (E) Has documented experience as a nurse assistant, emergency medical technician, or surgical technician in the past three (3) years; or (F) Has proof of completion of UAP training program in Missouri or another state which meets the requirements of this rule within the last three (3) years; or (G) Has completed a professional or licensed practical nursing program outside the United States and is awaiting the licensure examination in this country.

(4) The hospital training policy for UAPs shall meet the following **faculty qualifications** and responsibilities: (A) A registered professional nurse shall be designated as the course coordinator and shall be responsible for all aspects of the course, and must supervise all classroom and clinical instruction; (B) **Instructors shall hold a current license or temporary permit to practice as a registered professional nurse** in Missouri or in another Nurse Licensure Compact state and have a minimum of two (2) years of nursing experience in an acute care, long-term care, or ambulatory surgery facility within the prior five (5) years, or an experience as a clinical faculty member in a nursing program within the prior five (5) years. An instructor's nursing license shall not be under current disciplinary action; (C) A clinical supervisor's or preceptor's nursing license shall not be under current disciplinary action; and (D) **UAPs who have satisfied the training requirements of this rule and Licensed Practical Nurses may assist with the clinical practicum** under the direction of the course coordinator.

(5) A hospital or ambulatory surgical center that provides training for UAPs shall meet the following training site requirements: (A) Provide designated space sufficient to accommodate the classroom teaching portion of the course or have a written agreement with another acute care hospital, an area vocational-technical school, a high school offering a health service occupation program, a community college, or a provider agency to provide the classroom portion of the course; (B) Provide on-the-job clinical practicum or have a written agreement with one (1) or more hospitals or ambulatory surgical centers in their vicinity to do so; (C) Assess and review the program and outcomes of any training provided by another facility to ensure that all of the requirements of this rule have been met; (D) Maintain, either electronically or on paper records of course completion and competency for a minimum of three (3) years. Records shall be signed and dated by the course coordinator and each of the instructors and clinical supervisors verifying classroom time, clinical time, and competency for each student; and (E) Provide a signed copy of the course completion and competency record to the student, that includes the elements in subsection (5)(D) of this rule.

(6) The UAP **training shall be completed within ninety (90) days of employment** for any individual who is hired as a UAP. A UAP shall not work in direct patient care, except as part of their supervised practicum, until the entire UAP training requirements have been met.

19 CSR 30-20.136 Respiratory Care Services

(1) Respiratory care services, if provided, **shall be under the medical direction of a qualified physician member of the medical staff** and appointed by the governing body. The director shall

be responsible for implementing rules of the medical staff governing the quality and scope of respiratory care services.

(2) Respiratory care services shall be integrated within the total hospital organizational plan.

(3) Respiratory care services shall be under the direction of a licensed respiratory care practitioner or a registered professional nurse with relevant education and experience. When the director is not a licensed respiratory care practitioner, a licensed respiratory care practitioner shall be employed on a parttime consultant basis.

(4) Therapy shall be administered in accordance with the orders of a qualified and licensed practitioner and shall be documented in the patient's medical record.

(5) Respiratory care services shall be provided by qualified personnel as specified by the medical staff.

(6) Approved written policies and procedures which define and describe the scope and conduct of respiratory care shall be reviewed and kept current per hospital policy and readily available to staff.

(7) Personnel administering respiratory therapy services shall evaluate and reevaluate the therapy administered and this shall be documented in the patient's medical record.

(8) Space and equipment shall be provided to meet the needs of respiratory care services. Space, supplies, and equipment shall be maintained to ensure patient safety.

(9) There shall be a process for the review and evaluation on a regular basis of the quality and appropriateness of respiratory care services provided.

19 CSR 30-20.142 Variance Requests

(1) Requests for variance from the requirements of 19 CSR 30-20.015 through 19 CSR 30-20.140 shall be in writing to the Department of Health and Senior Services. Department determinations in response to variance requests shall be in writing and both requests and determinations shall be made a part of the Department of Health and Senior Services permanent records for the facility. (A) Requests shall contain at a minimum— 1. The section number and text of the rule in question; 2. Specific reasons why compliance with the rule would impose an undue hardship on the operator, including an estimate of any additional cost which might be involved; 3. An explanation of the extenuating factors which may be relevant; 4. A complete description of the individual characteristics of the facility or patients or any other factors which would fulfill the intent of the rule in question to safeguard the health, safety, and the welfare of the patient, staff, or public if the variance from the requirement is granted; and 5. A length of time the variance is being requested.

(2) The department's written determination shall identify a variance expiration date, if approved. The facility may re-apply for a variance up to ninety (90) days prior to the expiration of a department-approved variance.

(3) Any facility granted a variance by the department shall inform the department in writing if the conditions warranting the variance change. This written notification to the department shall be made within thirty (30) days of the change affecting the variance. The department may revoke the granted variance if the changes in conditions detrimentally impact the health, safety, and the welfare of the patient, staff, or public, as determined by the department.

(4) All previously approved variances shall be submitted at the time of annual licensure renewa

A Review of Senate Bill 808 and the Revised Class B Hospital Pharmacy Permit

**Missouri
Board of Pharmacy**



**Missouri
Department of Health
and Senior Services**

January 23, 2015

Presenters

Missouri Board of Pharmacy

- Kimberly Grinston, J.D. – Executive Director
- Tom Glenski, R.Ph. – Chief Inspector

Missouri Department of Health and Senior Services

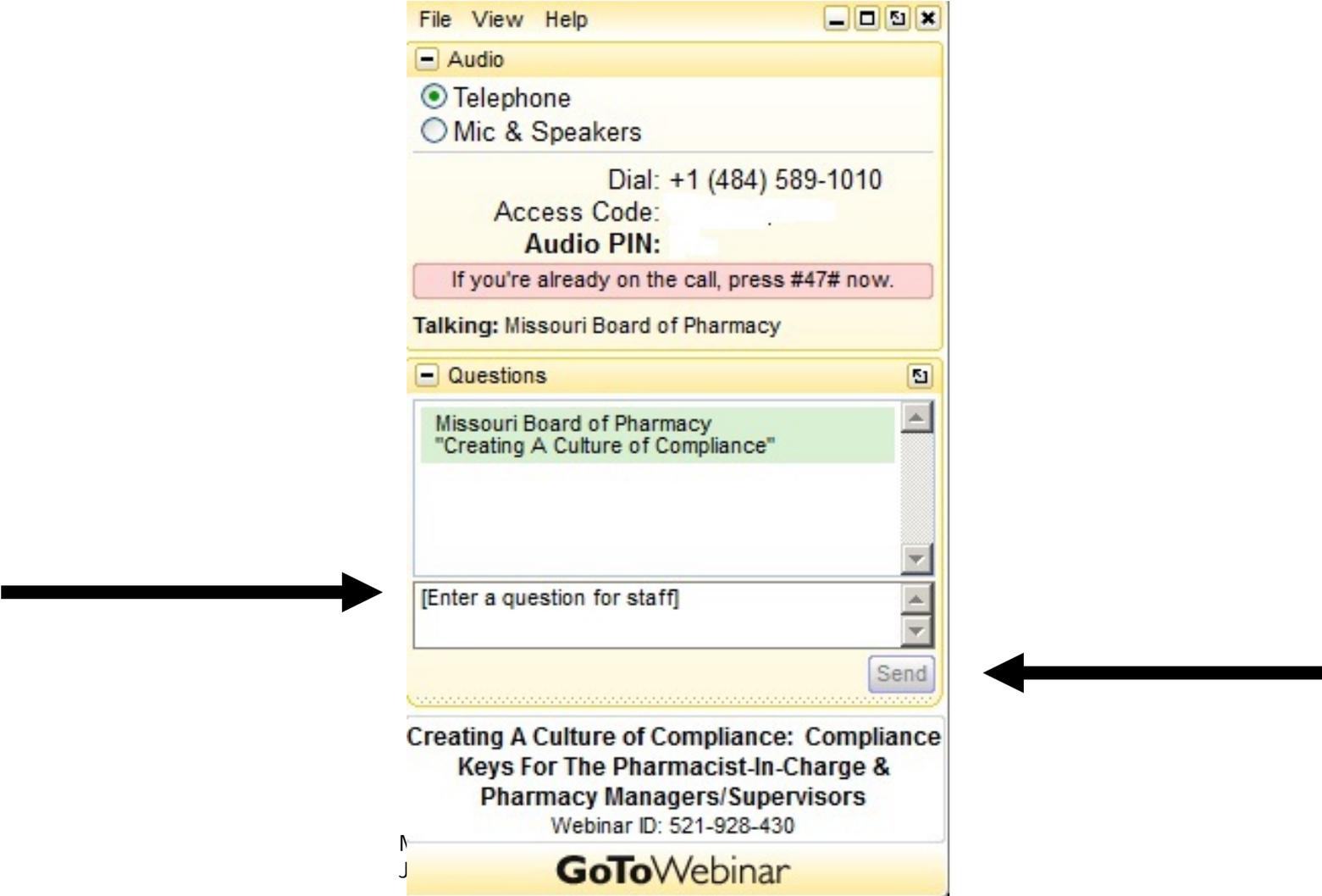
- Dean Linneman, - Deputy Division Director
Division of Regulation and Licensure

Program Objectives

- Review Senate Bill 808 effects on the practice of pharmacy in hospital settings
- Explain the revised Class B Hospital Pharmacy permit
- Answer related questions

No pharmacy continuing education credit is being offered for this program

How to Ask a Question



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SB 808

- Revised Class B Hospital ~~Outpatient~~ Pharmacy
 - Owned, managed or operated by a hospital
 - Includes pharmacy located in a clinic or facility under common control, management, or ownership of the same hospital or hospital system

SB 808

Definitions:

- "Hospital", a hospital as defined in section 197.020
- "Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system

SB 808

- Does not change jurisdiction of either DHSS or BOP within a hospital
- Hospital pharmacies solely providing drugs for patients within the hospital still require no BOP license
- Joint rulemaking between DHSS and BOP governing medication distribution and MTS by a pharmacist within a hospital
- Gives BOP authority to investigate complaints about individual BOP licensees within a hospital

SB 808

- Require BOP MTS certificate for pharmacists performing MTS within hospital
- No BOP drug distributor license required to distribute drugs from Class B permit to hospital clinic or facility for patient care

SB 808

- Allows prescription labeling by unique identifier instead of sequential number
- Allows use of orders versus prescriptions by Class B pharmacy
 - Did **not** address generic substitution of such orders
 - Seek guidance from your legal counsel concerning substitution

SB 808

"Medication order", an order for a legend drug or device that is:

(a) Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee; and

(b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;

"Patient", an individual receiving medical diagnosis, treatment, or care at a hospital or a hospital clinic or facility.

SB 808

Creation of advisory committee to review and make recommendations to all BOP/DHSS joint rules

- Seven members, designated by
 - MHA (2)
 - MSHP (1)
 - MPA (1)
 - DHSS (2)
 - BOP (1)
- BOP awaiting designations

Class B Hospital Pharmacy

- No longer limited to DHSS licensed premise
- Can be off-site hospital clinic or facility
- Can use orders instead of two-line prescription
- Can use hospital's order numbering system
- For distributions to hospital clinics and facilities, if exceed 5%, no drug distributor license required

“Inpatient” vs. “Outpatient”

- Various meanings
- Avoid use of terms
- BOP jurisdiction interpretation:
 - A drug prepared within and administered to a patient within the DHSS licensed hospital premises (regardless of patient billing status):
DHSS jurisdiction

QUESTIONS

Questions-Licensure

What areas are currently included in a DHSS hospital license and how can a hospital determine this?

DHSS Licensed Premises

197.60.2

Each license shall be issued only for the premises and persons or governmental units named in the application, and shall not be transferable or assignable except with written approval of the department of health and senior services....(1953)

DHSS Licensed Premises

197.052

An applicant for or holder of a hospital license may define or revise the premises of a hospital campus to include tracts of property which are adjacent but for a common street or highway, as defined in section 300.010, and its accompanying public right-of-way. (2010)

DHSS Licensed Premises

Rule Revision Draft Language:

Hospital definition:

(A) 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;
- (3) 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;

(B) The term "hospital" does not include convalescent, nursing, shelter or boarding homes as defined in chapter 198, RSMo.

DHSS Licensed Premises

Rule Revision Draft Language:

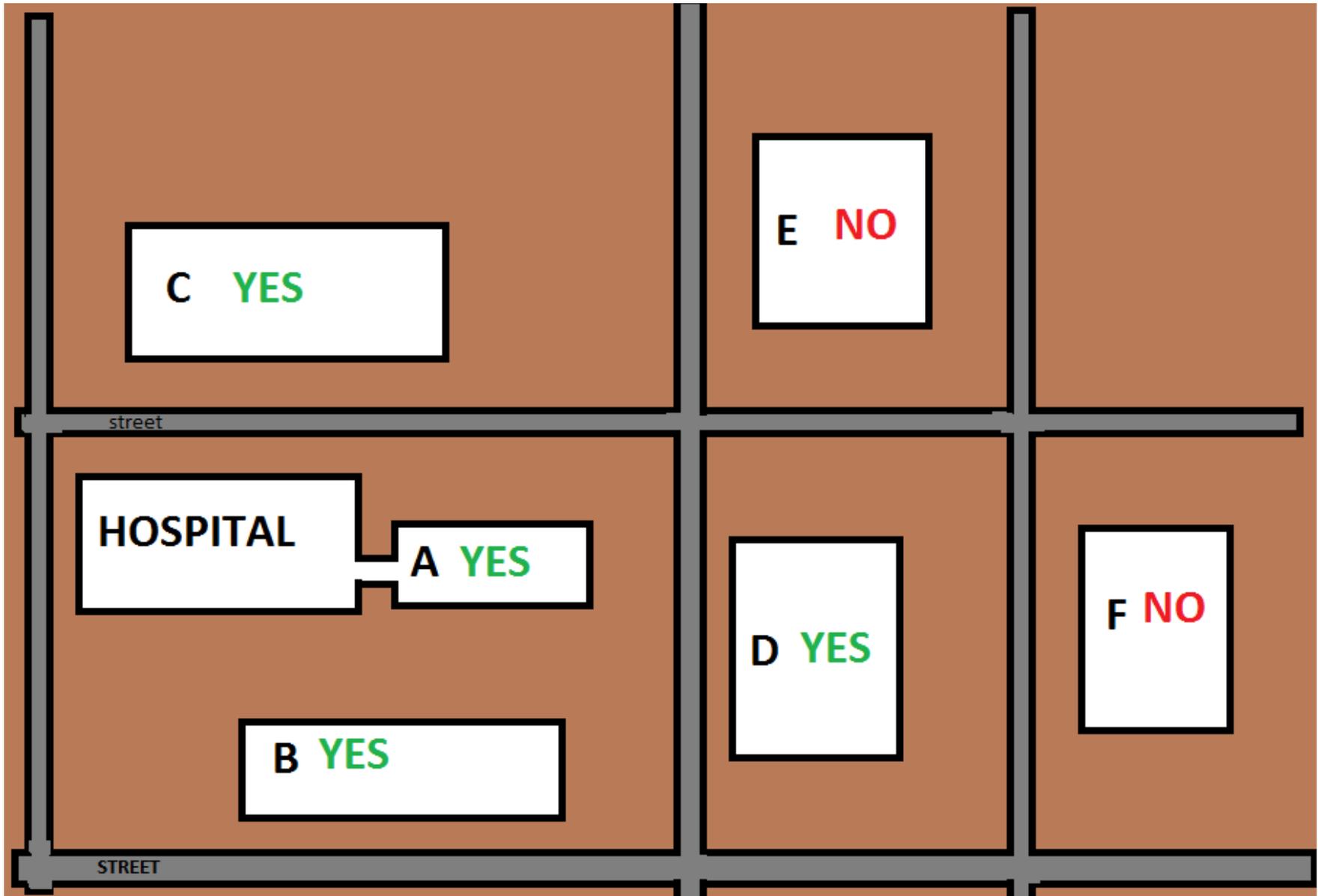
Hospital premises:

- (1) Buildings located on tracts of property which are adjacent to the hospital but for a common street or highway and its accompanying right-of-way may be included in the hospital's license if they meet subsection (A)(1) - (2) above.

DHSS Licensed Premises

- Premises ≠ Hospital campus
- Premises ≠ Hospital system
- Premises ≠ Corporate structure
- Premises ≠ CMS Certification Number (CCN)
- Premises ≠ Patient billing status
- Premises ≠ Provider employment status
- Premises ≠ Other DHSS license (ASC, LTCF)
- Premises ≠ Space rented to other entity

Possible License Scenarios



Questions-Licensure

How can a hospital determine if a clinic, infusion center or other non-inpatient area qualifies for a Class B license?

Statutory Definition

- 338.165

"Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system

- Seek legal guidance in determination, especially for joint ownership or private entity lease

Questions-Licensure

What defines the Class B “licensed area” in a hospital pharmacy, and can a hospital include more than one “area” in a Class B license?

Questions-Licensure

Are there any restrictions on mixed inpatient/outpatient activities or use of common stock for inpatient/outpatient orders/prescriptions in a Class B inpatient pharmacy?

Questions-Licensure

What defines the Class B licensed area in a clinic, and are there restrictions on access by other licensed practitioners?

Questions-MTS

Is a MTS certificate required for a pharmacist to perform routine inpatient “medication order management” procedures?

Statutory Requirement

338.165

4. All pharmacists providing medication therapy services shall obtain a certificate of medication therapeutic plan authority as provided by rule of the board.

Questions-MTS

Can non-employee pharmacists be authorized for hospital MTS protocols, e.g. pharmacists providing remote pharmacy order review and other clinical pharmacy services, including out-of-state pharmacists?

Remote Order Verification

- Pharmacist located in Missouri
 - Hold MO pharmacist license
 - If working outside of pharmacy or hospital, must comply with 20 CSR 2220-2.6055 *Non-Dispensing Activities*
- Pharmacist located outside of Missouri
 - Pharmacist must hold MO pharmacist license, or
 - Must be working in pharmacy holding MO non-resident permit
- Class J is not required on the pharmacy permit
- Remote supervision of technicians is not allowed

Questions-MTS

When is credentialing and privileging required for MTS protocols?

Questions-MTS

Can the same MTS protocols be used for both inpatients and outpatients?

BOP MTS Regulation

20 CSR 2220-6.060; 6.070; 6.080

Requirements

- General
- Physician
- Protocol
- Drug modification
- Recordkeeping

Questions-Drug Distribution

Can a hospital that has a Class B license distribute freely between all facilities within the health system?

Questions-Drug Distribution

Can a hospital that does not have a Class B license or drug distributor license distribute to a hospital-owned clinic or fill medication orders for another hospital owned by the same health system?

Questions-Rules

What will be the process for developing and promulgating the new joint rules?

Questions-Rules

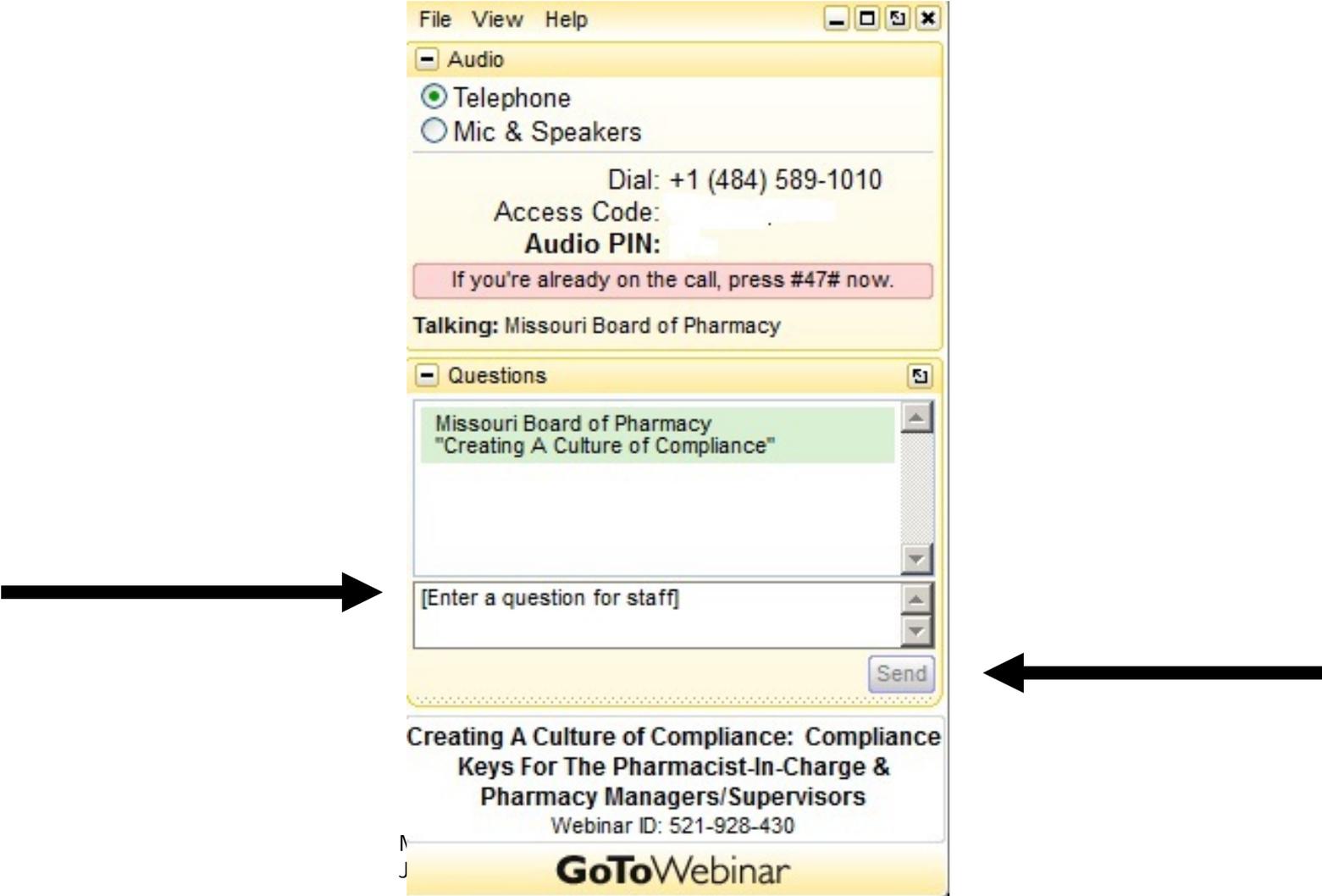
When will the Joint Rule Making Committee be appointed?

Questions-Rules

When will the proposed DHSS hospital pharmacy services rules be sent to the Secretary of State for publication as proposed rules?

**QUESTIONS
FROM PARTICIPANTS**

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