

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

**May 6, 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  
Daniel Good, R.Ph.  
James Gray, R.Ph.  
Colby Grove, R.Ph.  
Neil Schmidt, R.Ph.  
Greg Teale, R.Ph.

**Committee Members Absent**

Kevin Kinkade, 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 9:02 a.m. and roll-call was taken of meeting attendees.

**Agenda Item # 1:** Kimberly Grinston reported minutes from the January, February and March 2016, meetings have been included for review and approval. No recommended changes were suggested. **A motion was made by Daniel Good, seconded by Greg Teale, to approve the January 11, 2016, minutes as presented. The motion passed 5:0:0:1 with roll call vote as follows:**

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

**A motion was made by Daniel Good, seconded by Greg Teale, to approve the February 24, 2016, minutes as presented. The motion passed 5:0:0:1 with roll call vote as follows:**

James Gray – yes  
Daniel Good – yes

Neil Schmidt- yes  
Colby Grove- yes

Greg Teale – yes  
Kevin Kinkade - absent

A motion was made by James Gray, seconded by Neil Schmidt, to approve the March 2, 2016, minutes as presented. The motion passed 5:0:0:1 with roll call vote as follows:

James Gray – yes  
Daniel Good – yes

Neil Schmidt- yes  
Colby Grove- yes

Greg Teale – yes  
Kevin Kinkade - absent

**Agenda Item # 2:** Bert McClary asked for additional questions for the upcoming Board of Pharmacy/Dept. of Health and Senior Services webinar. Greg Teale indicated he is still accepting suggestions and believes the Committee should identify issues that are still unanswered in lieu of a broad overview of all previous webinar questions. Sarah Wilson commented she would attempt to survey hospital pharmacy directors and would likely have responses back in a week or less. Greg Teale commented that some of the webinar questions would likely require discussion during the Board's strategic planning meeting. Examples given included questions regarding automated dispensing cabinets in Class B infusion centers and transferring medication to licensed physicians/physician offices. General consensus to host the webinar at the end of August/early September. Tom Glenski stated he would talk with DHSS to confirm the date and questions.

**Agenda Item # 3:** Bert McClary introduced the topic and asked for comments. Greg Teale indicated large academic medical centers with central distribution will likely provide comments to the FDA as it appears some of these entities may now need to be registered as 503(B) entities.

**Agenda Item # 4:** Kimberly Grinston commented the Board will be voting on the draft sterile compounding emergency and amended rule during its upcoming conference call. Bert McClary commented Committee members previously reviewed a more extensive draft and stated he did not see any major concerns during his preliminary review. James Gray provided the following additional comments/suggestions:

- A suggestion was made to modify the language regarding monitoring of pressure differential results to clarify that pressure differential monitoring is not mandatory for all sterile compounders.
- Mr. Gray suggested amending the language to allow sterile alcohol and other equivalent or superior disinfectants. Mr. Gray remarked other disinfectants with sporicidal properties are currently in use.
- Mr. Gray indicated three (3) media-fill units during initial staff training is not a USP requirement and is only mentioned in USP as an example. Mr. Gray recommended changing the language to be consistent with USP.

No additional comments/changes were suggested.

**Agenda Item # 5:** Chairman McClary introduced the topic and suggested that Committee members view this agenda item as two separate issues: (1) the regulation

of Class B pharmacies and (2) the regulation of hospital owned clinics that are located outside of the hospital. Tom Glenski stated the proposed draft was initially intended to address Class-J issues and remarked that the Board received reports that mail-order pharmacies would not send medication to hospitals/clinics because they either didn't want to or couldn't comply with Class-J requirements. Mr. Glenski noted the other issue involved dispensing medication for pharmacist administration on site. Greg Teale commented this issue has become more prevalent since many insurers require white-bagging and prohibit shipment directly to the patient. Neil Schmidt noted that pharmacies may not be aware that the patient is coming or that medication is being shipped to the pharmacy. Kimberly Grinston stated the draft rule was placed on hold because staff did not feel they were fully aware of the hospital/Class-J issues. Tom Glenski clarified the proposed rule was intended to address entities that are not part of the DHSS hospital license and indicated the Board's historical position has been that true hospital pharmacies are not required to have a Class-J permit to receive a prescription from another pharmacy. Bert McClary commented the idea of receiving prescriptions from another pharmacy has been an issue since the 1990s.

James Gray suggested the other common scenario that may need to be addressed is offsite surgery centers and asked if preparations compounded by a hospital pharmacy can be sent to an offsite surgery center. Mr. Gray suggested these centers are really operating as hospital operating rooms. Tom Glenski suggested this scenario may implicate the sterile compounding rule.

Bert McClary asked Committee members to identify scenarios that may need to be addressed and suggested proposing a separate hospital rule similar to the Board's long-term care rule. Committee members were asked to e-mail compliance scenarios to Kimberly Grinston before the next meeting. Greg Teale indicated he has tried to survey hospitals but hasn't received strong feedback. Mr. Teale remarked that hospitals are operating safely and any proposed rule should allow hospitals to operate more efficiently and effectively. Sarah Wilson asked if a MHA survey could be included in the Board's e-alerts and Ms. Grinston stated the office could send a link to the survey on behalf of the Committee.

**Agenda Item # 9:** Bert McClary remarked DHSS and CMS have addressed this issue differently. Mr. McClary commented there is a governing body and then the medical staff that is a separate subunit of the hospital. The governing body has overall authority and delegates authority to the medical staff to establish criteria/procedures for privileging and medical staff membership with the governing body having final decision-making authority. Mr. McClary commented the current DHSS rule only allows medical staff membership for physicians, dentists, psychiatrists and podiatrists. Mr. McClary further remarked CMS language is confusing but allows medical staff membership to be extended to non-physicians which we currently consider to be mid-level practitioners. Mr. McClary proposed that the DHSS rule expressly provide that non-physicians can be medical staff members.

Mr. McClary further commented that section (18) of the DHSS Governing Body rule allows the granting of clinical privileges to non-physicians on an "out-patient" basis. Mr. McClary reported DHSS has proposed to modify the language to simply reference a

licensed practitioner which would include anyone licensed in Missouri under their applicable practice act. The proposed change would likely include pharmacists and collaborative nurse practitioners although it is unclear if respiratory therapists would be included. Mr. McClary asked if there are other categories of healthcare professionals who need clinical privileges and/or medical staff membership and asked how nurses and physician assistants are currently regulated. Julie Creach replied the proposed language is similar to language currently used for nurses/physician assistants and noted that any suggested changes would go to DHSS' working group for consideration. Bert McClary asked if the working group has proposed any additional changes to the Governing Body rule; Julie Creach indicated any proposed changes would likely be minor.

Greg Teale agreed with Mr. McClary's suggested rule changes and James Gray suggested proposing the changes as a formal recommendation from the Committee. Mr. Gray noted the proposed language is consistent with CMS language. **A motion was made by Greg Teale, seconded by James Gray, to submit Mr. McClary's proposed changes to 19 CSR 30-20.080 and 19 CSR 30-20.086 as a formal recommendation from the Committee. The motion passed 5:0:0:1 with roll call vote as follows:**

James Gray – yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Colby Grove- yes

Kevin Kinkade - absent

Kimberly Grinston will draft a letter for Mr. McClary's signature.

**Agenda Item # 10:** Bert McClary introduced the topic and indicated he has raised the issue of better defining the hospital premises/license with DHSS over the years. Mr. McClary commented there is minimal statutory language on this issue although DHSS has a proposed definition that hasn't been finalized. Tom Glenski indicated the Board usually asks DHSS if buildings are part of the hospital license. In most instances, Mr. Glenski indicated the hospital has either established a separate pharmacy or the hospital is sending medication to a practitioner in another building. Mr. Glenski stated he was informed by DHSS that it simply reviews the Board requests to determine if the building/pharmacy qualifies under the definition of hospital premises but DHSS is not checking to see if it has been notified that the building/facility is actually being used. Julie Creach commented that DHSS may not have received notification and the facility/area may have never been inspected for compliance with hospital standards. Bert McClary encouraged further collaboration. Mr. Glenski indicated he will be meeting with DHSS in June to discuss this issue further.

**Agenda Item # 11:** Kimberly Grinston stated final rule suggestions were provided to Dean Linneman and indicated copies would be provided to Committee members.

**Agenda Item # 12:** Bert McClary inquired about future meeting availability. Committee consensus to meet June 3, 2016, in Jefferson City at 10:00 a.m. and to meet by conference call on July 15, 2016, from 2:00 to 4:00 p.m. Suggested future agenda topics included: sterile compounding rule updates, the Board/DHSS webinar, changes

to the administration by medical prescription order rule, 2016 legislation and a possible hospital practice guide document.

**ADJOURNMENT**

A motion was made by Greg Teale, seconded by Colby Grove, to adjourn the meeting. The motion passed 5:0:0:1 with roll call vote as follows:

James Gray – yes

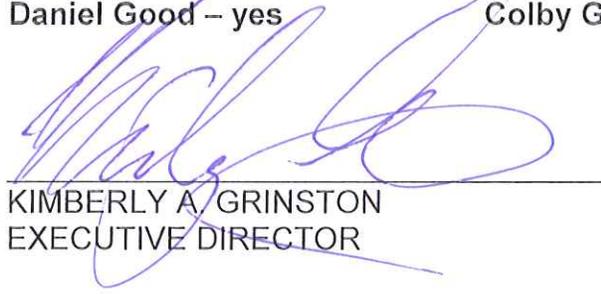
Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Colby Grove- yes

Kevin Kinkade - absent



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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.**~~

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

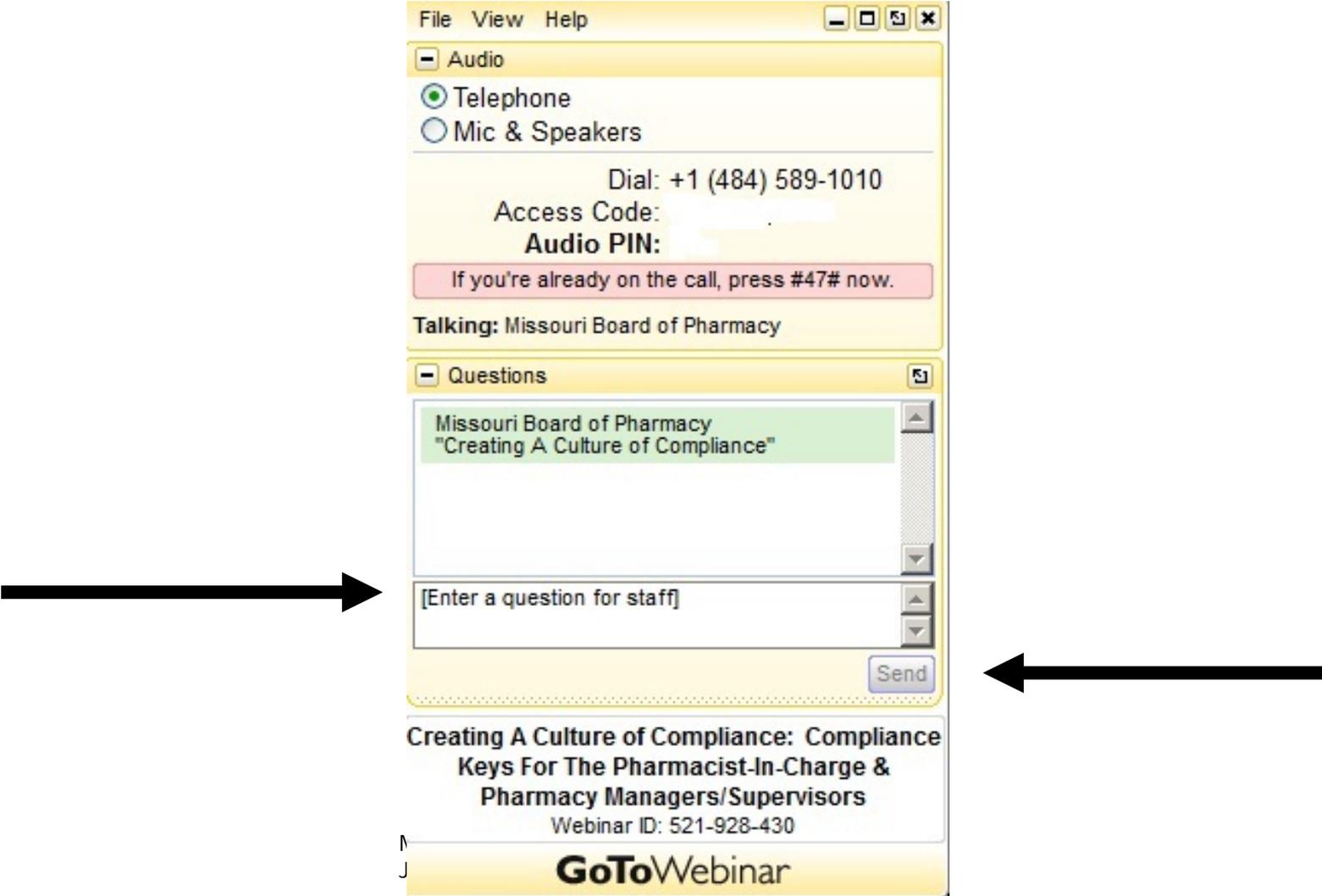
- Dean Linneman, - Deputy Division Director  
Division of Regulation and Licensure

# 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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Missouri Board of Pharmacy  
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Creating A Culture of Compliance: Compliance  
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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:

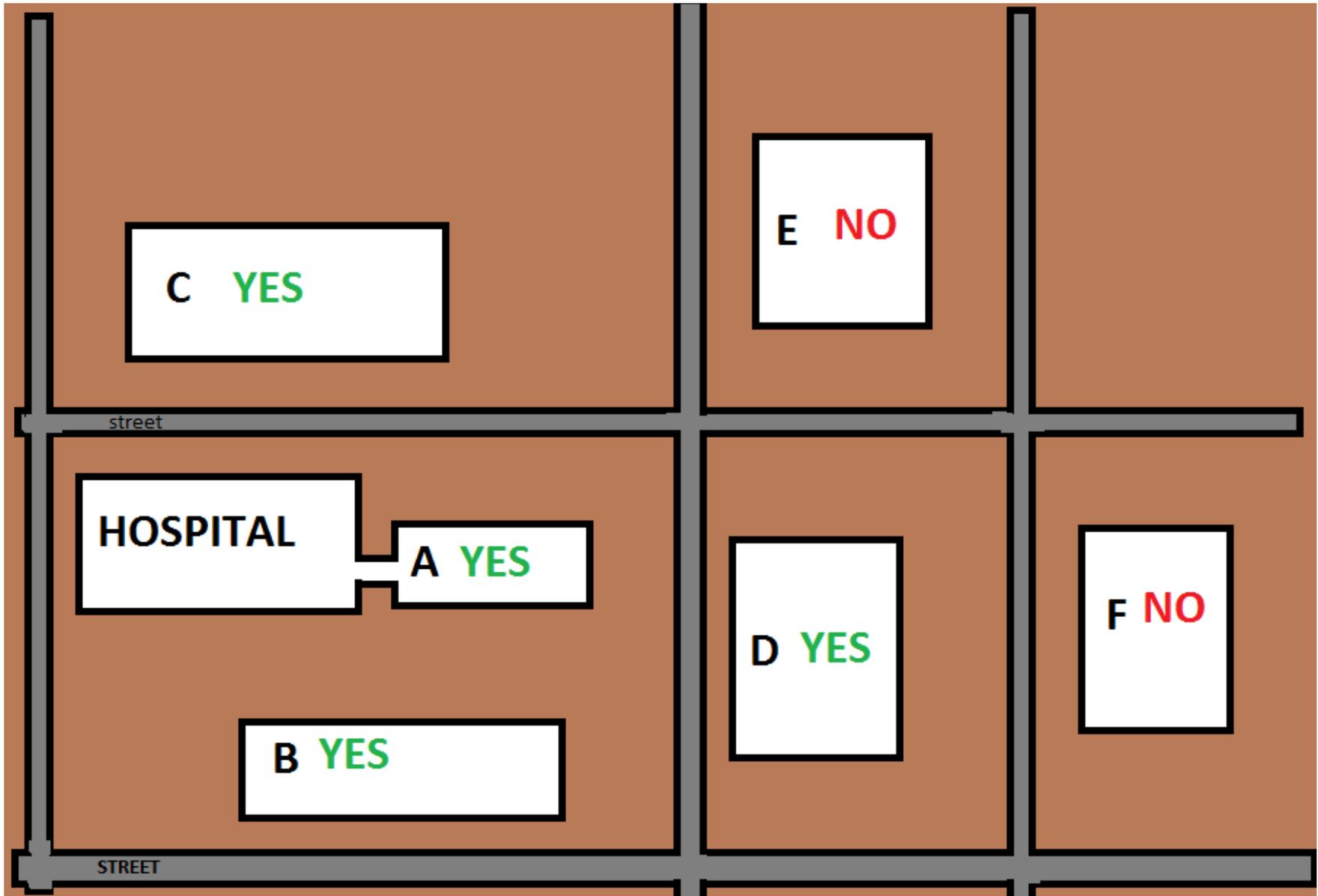
Hospital premises:

- (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

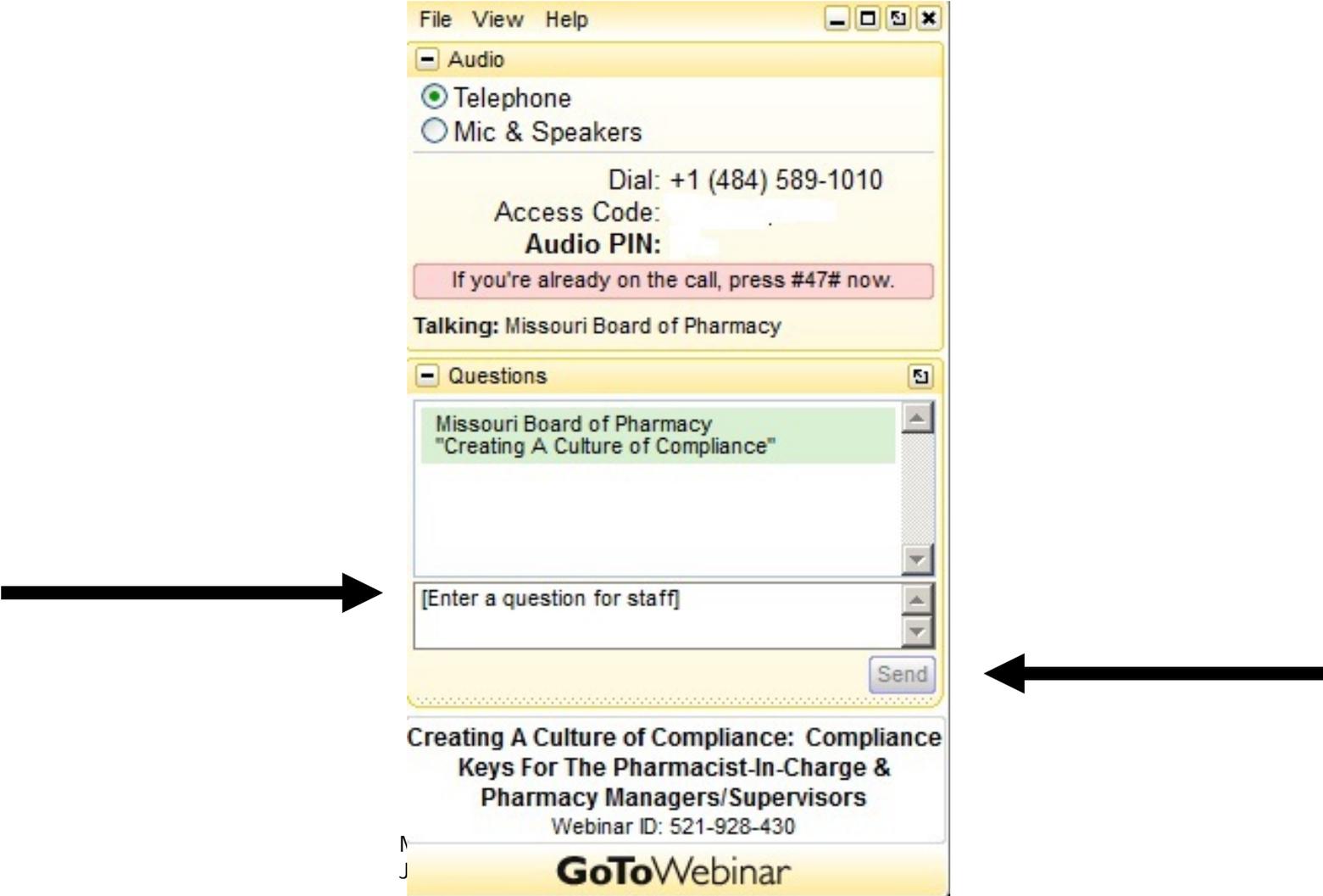
When will the Joint Rule Making Committee be appointed?

# 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**

# How to Ask a Question



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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.**

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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.*

DISCUSSION: The Advisory Committee asked to once again review potential questions for the SB 808 webinar. Committee members asked to review and finalize potential questions on the conference call.

The original webinar questions are below. Newly submitted questions are indicated in blue:

1. What areas are currently included in a DHSS hospital license and how can a hospital determine this?
2. How can a hospital determine if a clinic, infusion center or other non-inpatient area qualifies for a Class B license?
3. 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?
4. 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?
5. What defines the Class B licensed area in a clinic, and are there restrictions on access by other licensed practitioners?
6. Is a MTS certificate required for a pharmacist to perform routine inpatient “medication order management” procedures?
7. 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)?
8. When is credentialing and privileging required for MTS protocols?
9. Can the same MTS protocols be used for both inpatients and outpatients?
10. Can a hospital that has a Class B license distribute freely between all facilities within the health system?
11. 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?
12. What will be the process for developing and promulgating the new joint rules?

13. When will the Joint Rule Making Committee be appointed?

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

*15. What statutes/rules apply to non-DHSS licensed hospitals (eg DMH, Univ Hosp)?*

*16. What statutes/rules apply to inpatient practice at LTCF, ASC, inpatient hospice facilities that are part of a health system?*

*17. What is the difference between pharmacy collaborative practice and MTS?*

*18. What is the difference between traditional hospital protocols for medication use and MTS protocols?*

*19. Do any BOP limits on tech activities apply to hospital techs?*

# Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act Guidance for Industry

## ***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman, CDER Office of Unapproved Drugs and Labeling Compliance (OUDLC) at 301-796-3110.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Office of Compliance/OUDLC**

**April 2016  
Compounding and Related Documents**

# Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act Guidance for Industry

*Additional copies are available from:*

*Office of Communications, Division of Drug Information  
Center for Drug Evaluation and Research  
Food and Drug Administration*

*10001 New Hampshire Ave., Hillandale Bldg., 4<sup>th</sup> Floor  
Silver Spring, MD 20993-0002*

*Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353*

*Email: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)*

*<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>*

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Office of Compliance/OU DLC**

**April 2016  
Compounding and Related Documents**

*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

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1                   **Hospital and Health System Compounding Under the**  
2                   **Federal Food, Drug, and Cosmetic Act**  
3  
4                   **Guidance for Industry<sup>1</sup>**  
5  
6

7  
8 This draft guidance, when finalized, will represent the current thinking of the Food and Drug  
9 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not  
10 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the  
11 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible  
12 for this guidance as listed on the title page.  
13

14  
15  
16 **I. INTRODUCTION AND SCOPE**  
17

18 Pharmacies located within a hospital or standalone pharmacies that are part of a health system  
19 frequently provide compounded drug products for administration within the hospital or health  
20 system. Some of these compounders have registered with FDA as outsourcing facilities under  
21 section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and others  
22 are state-licensed pharmacies subject to section 503A of the FD&C Act. This guidance describes  
23 how FDA intends to apply section 503A of the FD&C Act to drugs compounded by licensed  
24 pharmacists or physicians in state-licensed hospital or health system pharmacies for use within  
25 the hospital or health system.  
26

27 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.  
28 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only  
29 as recommendations, unless specific regulatory or statutory requirements are cited. The use of  
30 the word *should* in Agency guidances means that something is suggested or recommended, but  
31 not required.  
32

33 **II. BACKGROUND**  
34

35 **A. Overview**  
36

37 1. Compounding Under the FD&C Act  
38

39 Sections 503A and 503B of the FD&C Act address human drug compounding.  
40

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<sup>1</sup> This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) and in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

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41 Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act  
42 in 1997, describes the conditions that must be satisfied for human drug products compounded by  
43 a licensed pharmacist in a State licensed pharmacy or Federal facility, or by licensed physician,  
44 to be exempt from the following three sections of the FD&C Act:

- 45
- 46 • section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP)  
47 requirements);
  - 48 • section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and
  - 49 • section 505 (concerning the approval of drugs under new drug applications or abbreviated  
50 new drug applications).

51  
52 A list of the conditions that must be met for a compounded drug product to qualify for the  
53 exemptions in section 503A of the FD&C Act appears in the guidance, *Pharmacy Compounding*  
54 *of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.<sup>2</sup>  
55

56 Section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, created a  
57 new category of compounders called *outsourcing facilities*. Section 503B of the FD&C Act  
58 describes the conditions that must be satisfied for human drug products compounded by or under  
59 the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for  
60 exemptions from three sections of the FD&C Act:

- 61
- 62 • section 502(f)(1);
  - 63 • section 505; and
  - 64 • section 582 (concerning track and trace requirements).

65  
66 The guidance, *For Entities Considering Whether to Register As Outsourcing Facilities Under*  
67 *Section 503B of the Federal Food, Drug, and Cosmetic Act* lists the conditions that are set forth  
68 in section 503B of the FD&C Act.

69  
70 Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B)  
71 of the FD&C Act, outsourcing facilities are subject to CGMP requirements, among other  
72 requirements under the FD&C Act (section 503B(a)).<sup>3</sup> In addition, outsourcing facilities will be  
73 inspected by FDA on a risk-based schedule (section 503B(b)(4)). An outsourcing facility is not  
74 required to be a licensed pharmacy and may or may not obtain prescriptions for identified  
75 individual patients.<sup>4</sup>

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<sup>2</sup> All FDA guidances are available on the FDA guidance Webpage at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. FDA updates guidances regularly. To ensure that you have the most recent version, please check this web page.

<sup>3</sup> FDA has issued a draft guidance for industry *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*. Once finalized, that guidance will represent the Agency's thinking on this topic.

<sup>4</sup> Although an outsourcing facility may send prescription drugs to health care facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the

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### **2. Compounding in Hospitals and Health Systems**

Compounded drug products can serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, or an elderly patient or a child who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available.

Hospital and health system<sup>5</sup> drug compounding and distribution practices vary. For example, some hospital pharmacies compound drugs only for use in the hospital in which the pharmacy is located (e.g., for the treatment of patients admitted to the hospital, or for use in the hospital’s emergency room), while other hospital and health system pharmacies compound and distribute their compounded drug products to other facilities within their health system (e.g., to other hospitals, clinics, infusion centers, or long-term care facilities within the health system for administration or dispensing).

In some cases, a hospital or health system pharmacy compounds drugs only after receipt of a prescription or order for an identified individual patient. Hospital and health system pharmacies may also compound drugs and distribute them within the hospital or health system before the receipt of a patient-specific prescription. The hospital or health system then holds the drug products until a patient presents with a need for the drug, for example in an operating room, where emergency procedures cannot be scheduled in advance, or in emergency departments.

Many hospitals and health systems purchase compounded drug products from compounders that have registered with FDA as outsourcing facilities under section 503B of the FD&C Act. Outsourcing facilities are subject to increased federal oversight through FDA inspection on a risk-based schedule, and quality standards (CGMP requirements) that help to assure the quality of their compounded drug products. Some hospital and health system compounders have registered with FDA as outsourcing facilities to serve as centralized compounding facilities where drug products are compounded with or without first receiving patient-specific prescriptions, and they then distribute the drugs within their health system or to affiliated health care facilities.

### **3. Risks Associated with Compounded Drug Products**

Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In

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requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

<sup>5</sup> FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of “health system” that applies to all sections of the FD&C Act. However, this is the definition of a “health system” used in section 506F of the Act concerning hospital repackaging of drugs in shortage.

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113 addition, licensed pharmacists and licensed physicians who compound drug products in  
114 accordance with section 503A are not required to comply with CGMP requirements.  
115 Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed  
116 physicians who compound drug products and seek to qualify for the exemptions under section  
117 503A of the FD&C Act for the drug products they compound because these compounders are not  
118 licensed by FDA and generally do not register their compounding facilities with FDA.  
119 Therefore, FDA is often not aware of potential problems with their compounded drug products  
120 or compounding practices unless it receives a complaint such as a report of a serious adverse  
121 event or visible contamination.

122  
123 In 2012, contaminated injectable drug products that a compounding pharmacy shipped to  
124 patients and healthcare practitioners across the country caused a fungal meningitis outbreak that  
125 resulted in over 60 deaths and over 750 cases of infection.<sup>6</sup> This was the most serious of a long  
126 history of outbreaks associated with contaminated compounded drugs. Since the 2012 fungal  
127 meningitis outbreak, FDA has investigated numerous other outbreaks and other serious adverse  
128 events, including deaths, associated with compounded drugs that were contaminated or otherwise  
129 compounded improperly.

130  
131 FDA has also identified many pharmacies that compounded drug products under insanitary  
132 conditions whereby the drug products may have been contaminated with filth or rendered  
133 injurious to health and that shipped the compounded drug products made under these conditions  
134 to patients and health care providers in large volumes across the country.<sup>7</sup> The longer a  
135 compounded sterile drug product that is contaminated is held by a pharmacist or physician before  
136 distribution, or the longer it is held in inventory in a healthcare facility before administration, the  
137 greater the likelihood of microbial proliferation and increased patient harm.

138  
139 As noted previously, compounders that elect to become outsourcing facilities must register with  
140 FDA, must comply with CGMP requirements, and are inspected by FDA according to a risk-  
141 based schedule. This mitigates the risk that their drug products will be contaminated or  
142 otherwise made under substandard conditions.

143  
144 Because compounded drugs have not undergone premarket review for safety, effectiveness, and  
145 quality, they should only be used when an FDA-approved product is not available to meet the  
146 medical needs of an individual patient. As described further below, the exemptions under  
147 sections 503A and 503B of the FD&C Act are only available to compounded drugs that meet  
148 certain conditions.

### **B. The Prescription Requirement in Hospitals and Health Systems**

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150  
151  

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<sup>6</sup> See <http://www.cdc.gov/HAI/outbreaks/meningitis.html>

<sup>7</sup> See FDA actions, including warning letters and injunctions, related to insanitary conditions at compounding facilities, on FDA's website at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm>

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152 As described above, compounded drug products are not approved and, therefore, do not undergo  
153 premarket review for safety, effectiveness, and quality. In addition, drug products compounded  
154 by licensed pharmacists and licensed physicians under section 503A of the FD&C Act are  
155 exempt from CGMP requirements. As reflected in the policies set forth below, FDA believes  
156 that the conditions in sections 503A and 503B provide important protections to patients,  
157 including those treated in a hospital or other facility within a health system, from the risks  
158 associated with compounded drugs and help ensure that compounders do not operate like  
159 conventional manufacturers. Therefore, FDA generally intends to apply these conditions to  
160 compounding in health system and hospital pharmacies, and sets forth an enforcement policy  
161 below regarding the prescription requirement in section 503A.

162  
163 The prescription requirement in section 503A ensures that drug products are only exempt from  
164 three key provisions of the FD&C Act designed to assure safety, efficacy, and quality if they are  
165 compounded for identified individual patients. However, as stated above, FDA recognizes that a  
166 hospital may need to maintain a supply of certain compounded drug products within the hospital  
167 but outside of the pharmacy (e.g., in an emergency department or operating room) in anticipation  
168 of a patient presenting with a critical need for the drug when there is no time for the hospital  
169 pharmacy to compound and provide the drug upon receipt of a prescription or order for that  
170 patient.

171  
172 FDA also recognizes that certain characteristics of hospital pharmacies differentiate them from  
173 pharmacies that are not owned and controlled by hospitals, and from conventional  
174 manufacturers. For example, generally, the scope of distribution of drug products compounded  
175 by hospital pharmacies is limited. Hospital pharmacies usually compound drug products based  
176 on orders from practitioners who work in the hospital, distribute the drug products only within  
177 the hospital or to related healthcare facilities under common ownership and control and located  
178 within close proximity to the hospital, and administer them only to patients within the hospital or  
179 healthcare facility. Because the hospital or healthcare facility and the pharmacy are under  
180 common ownership and control, the hospital or healthcare facility is responsible for both the  
181 compounding of the drug and treatment of the patient, and the cause of any compounding-related  
182 adverse events can be more readily identified. FDA believes that the policies set forth in this  
183 guidance, based on the way a hospital pharmacy normally functions with regard to compounding  
184 for its patients, will prevent hospital pharmacies from operating like conventional manufacturers.

185

### **III. POLICY**

#### **A. Hospital or Health System Compounding Under Section 503A of the FD&C Act**

189  
190 To qualify for the exemptions under section 503A of the FD&C Act from sections 501(a)(2)(B),  
191 502(f)(1), and 505(a), a drug product compounded by a licensed pharmacist in a state-licensed  
192 pharmacy or Federal facility, or by a licensed physician, must be compounded in accordance  
193 with all of the provisions of section 503A. Section 503A does not distinguish between stand-  
194 alone pharmacies and pharmacies within hospitals and health systems. Therefore, the provisions  
195 of section 503A apply to pharmacists, pharmacies, and physicians that compound drugs within a  
196 hospital or a health system that is not registered as an outsourcing facility under section 503B.

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197 Drug products compounded by a licensed pharmacist or licensed physician that are not  
198 compounded in accordance with all of the provisions of section 503A may be subject to  
199 regulatory action for violations of the new drug approval, adequate directions for use, and CGMP  
200 requirements of the FD&C Act.

201  
202 For example, under section 503A, a licensed pharmacist or a licensed physician within a hospital  
203 or health system must compound drug products for an identified individual patient. The  
204 compounding must either be (a) after the receipt of a valid prescription or order for an identified  
205 individual patient or (b) in limited quantities in advance of receipt of a valid prescription or order  
206 for an identified individual patient, and the drug must be distributed after receipt of the  
207 prescription or order.

208  
209 However, FDA does not intend to take action if a hospital pharmacy distributes compounded  
210 drug products without first receiving a patient-specific prescription or order provided that:

- 211
- 212 (1) The drug products are distributed only to healthcare facilities that are owned and  
213 controlled by the same entity that owns and controls the hospital pharmacy and that are  
214 located within a 1 mile radius of the compounding pharmacy;
  - 215 (2) The drug products are only administered within the healthcare facilities to patients within  
216 the healthcare facilities<sup>8</sup>, pursuant to a patient specific prescription or order; and
  - 217 (3) The drug products are compounded in accordance with all other provisions of section  
218 503A, and any other applicable requirements of the FD&C Act and FDA regulations  
219 (e.g., the drug products are not made under insanitary conditions (section 501(a)(2)(A))  
220 or misbranded (e.g., section 502(g)).

221  
222 The 1-mile radius in our policy is intended to distinguish a hospital campus from a larger health  
223 system. As explained in section II.B of this guidance, certain characteristics of hospital  
224 pharmacies distinguish them from conventional manufacturers. However, a health system  
225 pharmacy that compounds drug products without patient-specific prescriptions for facilities  
226 within its health system across a broader geographic area could function as a large manufacturing  
227 operation, but without the necessary standards to assure drug quality. If such a pharmacy  
228 contaminates or otherwise adulterates or misbrands a compounded drug, the drug has the  
229 potential to harm many patients. Outsourcing facilities, which are subject to CGMP  
230 requirements and other conditions that help to assure drug quality, can compound and distribute  
231 drug products to healthcare facilities nationwide without first receiving prescriptions for  
232 identified individual patients.

### **B. Hospital or Health System Compounding Under Section 503B of the FD&C Act**

234  
235  
236 A compounder can register as an outsourcing facility if it intends to provide compounded drugs  
237 to facilities such as other hospitals or clinics outside the 1 mile radius of the pharmacy in which  
238 the drug is compounded without first obtaining a prescription for an identified individual patient.

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<sup>8</sup> This does not include dispensing a drug product to a patient for use outside the hospital.

***Contains Nonbinding Recommendations***

*Draft — Not for Implementation*

239 To qualify for the exemptions under section 503B from sections 502(f)(1), 505, and 582 of the  
240 FD&C Act, hospitals and health system compounders that elect to register with FDA as  
241 outsourcing facilities must comply with all of the provisions of section 503B. Outsourcing  
242 facilities must also comply with CGMP requirements in section 501(a)(2)(B) of the FD&C Act.

# OFFSITE HOSPITAL OWNED CLINICS

DISCUSSION: The Advisory Committee discussed issues with hospital-owned clinics and asked if the Board would be able to draft a rule relating specifically to medication dispensing/distribution at a clinic that is outside of DHSS' jurisdiction. Board staff indicated a proposed draft of a rule was presented to the Board to exempt certain facilities from the Class-J requirements. The proposed rule did not address the additional concerns raised during previous Committee meetings.

Members of the Advisory Committee asked to review the previous draft and to further discuss what accommodations/changes should be made in the Board's rules for offsite clinics owned by a hospital.

**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 2—General Rules**

**EMERGENCY RULE**

**20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy**

*PURPOSE: The purpose of this rule is to establish minimum standards of operation for Class J: Shared Services Pharmacy, in compliance with House Bill 567 of the 91st General Assembly.*

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;
2. Maintain separate licenses for each location involved in providing shared services; and
3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(B) There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. Transfer of prescription information between two (2) pharmacies that are accessing the same real-time, on-line database pursuant to the operation of a shared service pharmacy operation shall not be considered a prescription transfer and, therefore, is not subject to the requirements of [4 CSR 220-2.120] **20 CSR 2220-2.120**.

(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:

1. A description of how the parties will comply with federal and state laws and regulations;
2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;

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3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;

4. The provision of adequate security to protect the confidentiality and integrity of patient information;

5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems; and

6. A designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190 and federal law. For purposes of § 338.059, RSM, the name and address of the pharmacy responsible for offering patient counseling shall be listed on the prescription label.

(3) A Class J Shared services permit shall not be required if a completed and labeled prescription is delivered from a Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional to the patient on the same premises or physical location as the pharmacy.

(A) The exemption recognized in this subsection shall only apply if a completed and labeled prescription is delivered to the receiving pharmacy that is ready for administration to the patient, provided that additional manipulation or compounding of the medication may be performed if necessary for proper administration. Medication administered by a pharmacist shall be performed in compliance with all applicable provisions of law.

(B) The receiving pharmacy shall maintain documentation of the medication received, the name and address of the pharmacy providing the medication, the date of receipt and the patient's name. If additional manipulation or compounding of the medication is performed by the receiving pharmacy, the product shall be treated as a prescription by the receiving pharmacy and shall comply with all applicable prescription requirements, including, all record keeping, compounding and labeling requirements.

(C) The receiving pharmacy shall be responsible for ensuring compliance with all applicable patient counseling requirements.

(D) For purposes of this rule, administration is defined as applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion or other means.

(E) Notwithstanding any other provision of this rule, licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security and record keeping requirements.

*AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and 338.210 and 338.220, RSMo Supp. 2001.\* This rule originally filed as 4 CSR 220-2.650. Original rule filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.650, effective Aug. 28, 2006.*

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\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951, amended 2001; 338.220, RSMo 1951; amended 1969, 1981, 1989, 1997, 1999, 2001; 338.240, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.

**3.00.91 Prescriptions dispensed by prescription drug outlets for delivery to consumers in other other outlet settings. When a drug has been dispensed pursuant to prescription order at a prescription drug outlet but has not been delivered to the ultimate consumer at an other outlet, the drug may be returned to stock only at the originating Prescription Drug Outlet, for subsequent redispensing provided that:**

- a. The prescription drug outlet complies with Board Rules 3.00.90(a), (b), and (c);**
- b. The storage conditions during the transport of the prescription to and from the other outlet do not in any way compromise the integrity or stability of the drug;**
- c. No controlled substance prescriptions may be returned to stock; and**
- d. No compounded or flavored prescription may be returned to stock.**

## Governing Body 19 CSR 30-20.080

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

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

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

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

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

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

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

~~(B) The mechanism shall include criteria for a review of an independent A practitioner's credentials shall be reviewed at least every two (2) years. At a~~

minimum, the **review** criteria shall include documentation of a current license, relevant training and experience, and competency.

## Medical Staff

### 19 CSR 30-20.086 Medical Staff in Hospitals

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

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

(2) Medical staff membership shall be limited to physicians, dentists, psychologists, ~~and podiatrists~~ **and other non-physician licensed practitioners. Non-physician practitioner medical staff appointments shall be within the scope and authority of each practitioner's current Missouri license and practice act. They shall be currently licensed**

~~to practice their respective professions in Missouri.~~ The bylaws of the medical staff shall include the procedure to be used in processing applications for medical staff membership and the criteria for granting initial or continuing medical staff appointments and for granting initial, renewed or revised clinical privileges.

(3) No application for membership on the medical staff shall be denied based solely upon the applicant's professional degree or the school or health care facility in which the practitioner received medical, dental, psychology or 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~~ **or other licensed practitioner** requesting staff membership shall submit a complete written application to the chief executive officer of the hospital or his designee on a form approved by the governing body. Each application shall be accompanied by evidence of education, training, professional qualifications, license and and other information required by the medical staff

bylaws or policies.

(5) Written criteria shall be developed for privileges extended to each member of the staff **and to other licensed practitioners granted clinical privileges**. A formal mechanism shall be established

for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff. The mechanism shall include an inquiry of the National Practitioner Data Bank. Bylaws of the medical staff shall provide for hearing and appeal procedures for the denial of reappointment and for the denial, revocation, curtailment, suspension, revocation, or other modification of clinical privileges of a member of the medical staff.

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

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

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

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

(10) The organized medical staff shall meet at intervals necessary to accomplish its required functions. A mechanism shall be established

for monthly decision-making by or on behalf of the medical staff.

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

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

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

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

*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.*