

OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Conference Call

December 14, 2015

The Missouri Hospital Advisory Committee met via conference call in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed. The meeting was called to order by Chairman Bert McClary at 10:03 a.m. on December 14, 2015.

Committee Members Present

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

Staff Present

Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector

Others Present

Christian Tadrus, R.Ph., Board Member
Sharon Burnett, Missouri Hospital Association
Ron Fitzwater, Missouri Pharmacy Association
William Koebel, Missouri DHSS¹

Chairman McClary opened the conference call at 10:03 a.m. and initially asked Kimberly Grinston about the procedure for Board review of the Advisory Committee's recommended changes to the DHSS hospital pharmacy rule. Ms. Grinston indicated the Committee's recommendations would likely be submitted to the Board in January to assess which recommendations should be officially forwarded to the Missouri Department of Health and Senior Services (DHSS).

Agenda Item # 1: Kimberly Grinston reported draft minutes from the November 6, 2015, meeting group have been included for informational purposes and suggested holding final approval of the minutes until committee members have had sufficient time to review. Committee consensus to hold approval of the November 6, 2015, minutes as suggested. Chairman McClary provided the following corrections to the draft minutes:

- Section (9) was changed to reference controlled substances stored "outside of the pharmacy" in both subsections (A) and (B).

¹ Attendee Sharon Burnett left the call at 10:45 a.m.; Christian Tadrus left the call at 11:00 a.m.

- The last sentence in section (12) should provide: "Where the risk of harm is significant, patients receiving the medication and the prescriber shall be notified."
- Section (18) should reference the medication "record" and not the medication "profile".

Kimberly Grinston also reported that requested revisions to the 9/25/15 minutes have been incorporated and included for Committee review. Daniel Good indicated the 9/25/15 minutes incorrectly identify him as absent during a Committee vote. Kimberly Grinston indicated revisions would be made as suggested.

Agenda Item # 2: The Working Group proceeded to review DHSS' proposed draft hospital pharmacy rule, 19 CSR 30-20.100. The rule changes recommended by the Advisory Committee have been incorporated into the document attached hereto. In addition to the changes noted therein, the following discussion was also held:

- Section (8): Bert McClary suggested asking for Board clarification of "persons involved in compounding" and asked if pharmacy technicians should be identified/documented in the hospital's records. Neil Schmidt commented the Board would likely hold both the pharmacist and technician responsible for errors and may look for documentation of both parties. Greg Teale indicated some electronic systems may not be currently able to document the technician on patient-specific prescriptions. Bert McClary asked if a distinction should be made for recording technicians dispensing/distributing sterile compounds as opposed to technicians dispensing routine oral dosages. James Gray suggested using the term "responsible for" to avoid confusion.

James Gray also commented that the use of dispensing in section (8) is confusing since dispensing generally applies to retail pharmacy. Mr. Gray asked if stocking Pyxis cabinets or providing medication to nurses would be considered "dispensing." Neil Schmidt suggested including "dispensing or other distribution." Committee consensus to change language to persons "responsible for" in lieu of "persons involved in" and to reference "dispensing or other distribution."

- Section (9): Kevin Kinkade commented the inventory requirements may present a challenge for smaller hospitals who may not have full-time pharmacist staff. Neil Schmidt commented that smaller critical access and community hospitals will likely have a smaller inventory and may be able to comply. Greg Teale asked if pharmacy systems that conduct continuous or daily inventory reconciliations would be compliant and asked if all inventories would be required on the same date. Mr. Teale indicated this issue was raised in a recent Board inspection. Bert McClary commented the inventory issue could be clarified in a regulatory guidance document. Committee consensus to make no additional changes to the inventory requirements.

- Section (34): Bert McClary commented this section was drafted after significant discussion on medications that are ordered prior to having an official order for the patient. Chairman McClary commented this practice generally occurs in emergency and ICU settings where quick action is required. Chairman McClary indicated section (34) mirrors the Centers for Medicare & Medicaid Services (CMS) requirements. No suggested changes were made.

- Section (35): Bert McClary indicated this section also incorporates language from CMS. Greg Teale asked if the policy and procedure requirements should be moved to section (1) of the rule for consistency. Bert McClary suggested retaining the policy and procedure language because it is more specific. Bert McClary indicated section (35)(E) is a direct reference to scribes and asked if the language should be more inclusive. Greg Teale indicated the pharmacist may not know who enters the order as this process is generally handled by Information Technology staff. Neil Schmidt suggested adding scribes in the language as an example. James Gray cautioned against specifically referencing scribes because the terminology might change. Kevin Kinkade suggested including a reference to scribes in a guidance document. Committee consensus not to recommend any changes but to suggest future regulatory guidance.

- Section (37): Neil Schmidt asked if the language would include nursing students still training under a preceptor. Bert McClary indicated section (37)(G) would address nursing students. Greg Teale asked if other healthcare workers such as radiology technologists would be included under this section and asked if the rule language should require that persons administering medication must be licensed or operating in a field that is under the governance of a national organization with practice standards. Mr. Teale also asked if there was a central regulatory resource for determining which healthcare professionals have authority to administer or that include medication administration within their scope of practice. Neil Schmidt asked about the applicability of the language to medical technicians who may administer contrast media without a physician in the room, especially for interventional radiology. Bert McClary commented the supervising physician would need to be readily available and suggested that the regulatory agencies may be able to provide additional clarification in a guidance document.

- Section (38): Bert McClary indicated the initial goal of this section was to include language that made the pharmacy responsible for storing all medications, however, the original DHSS rule review group did not agree. Neil Schmidt suggested clarifying the destruction language to ensure compliance with BNDD and DEA standards. Kevin Kinkade asked if the language would allow use of a reverse distributor which Bert McClary indicated should be encouraged. Daniel Good asked if rule language would allow participation in a law enforcement return program. Further discussion was held regarding the legality of returning controlled substances brought in to the hospital by a patient on patient discharge and the legality of providing controlled substances brought into the hospital by the patient to the patient's family after the patient expires. Kimberly Grinston indicated she would consult with Scott Collier with the DEA for guidance.

- Section (39): Kevin Kinkade asked if the language needed to reference sentinel events or include root-cause-analysis (RCA) language that might be similar to the Institute for Safe Medication Practice's suggested standards. Mr. Kinkade commented CMS may ask about an RCA for a significant event. Bert McClary suggested that language governing sentinel events or RCA requirements would be better covered in another section of DHSS' rules applicable to the entire hospital. Daniel Good indicated the proposed hospital pharmacy rule would exceed the \$ 500 fiscal note threshold.

Agenda Item # 5: Bert McClary asked about scheduling future meeting dates. Neil Schmidt indicated he is available on Monday, Wednesday and Friday. Kevin Kinkade indicated he is available Monday, Wednesday and Thursday. Committee consensus to meet in Jefferson City on 1/11/16 at 10:00 a.m. The Committee agreed by consensus to review the final suggestions to the DHSS hospital pharmacy rule at the January 11th meeting.

Committee Member Neil Schmidt left the meeting at 11:57 a.m.

Agenda Item # 4: Bert McClary asked the committee to forward any suggestions on future meeting topics and to identify any priority topics committee members would like to address. Chairman McClary identified the following personal priority topics:

- *First Priority:* The Board's administration by prescription order rule. Chairman McClary indicated the current rule was based on the Board's immunization rule and incorporates a retail standard. Chairman McClary commented questions still exist regarding emergency departments and pharmacist authority to administer in the emergency room. Chairman McClary indicated he would like to invite additional attendees to participate in the administration by medication order discussion, including, pharmacist Jeremy Hampton.
- *Second Priority:* SB 808 and Class B pharmacy implementation, and
- *Third Priority:* Pharmacist medication therapy services.

MOTION TO ADJOURN

At approximately 12:15 p.m., Kevin Kinkade made a motion, seconded by Greg Teale, to adjourn the December 14, 2015, meeting. The motion passed 4:0:0:1 with roll call vote as follows:

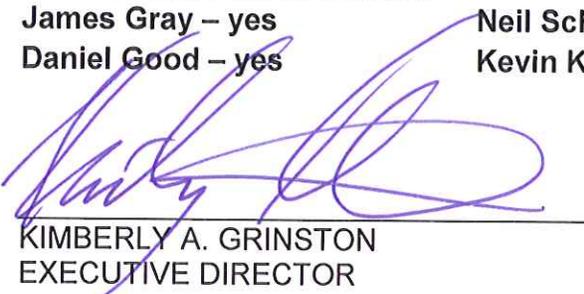
James Gray – yes

Daniel Good – yes

Neil Schmidt- absent

Kevin Kinkade - yes

Greg Teale – yes



KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved: 1-11-2016

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 with 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 in an automated dispensing system outside of
122 the pharmacy 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.

131

132 *[(11)]* (10) Controlled *[substance storage areas in the pharmacy]* substances shall be
133 *[separately]* stored in locked *[and]* compartments separate from non-controlled substances.
134 Controlled substances in the pharmacy shall be accessible only to authorized pharmacy staff.
135 *[Reserve supplies of all controlled substances in the pharmacy shall be locked.]* Controlled
136 *[substance storage areas]* substances outside the pharmacy shall be *[separately locked and]*
137 accessible only to persons authorized to administer *[them]* controlled substances and to
138 authorized pharmacy staff.

139
140 [(12) Authorization of access to controlled substance storage areas outside of the pharmacy,
141 shall be established by the director of pharmacy services in conjunction with nursing and
142 administration. The distribution and accountability of keys, magnetic cards, electronic codes or
143 other mechanical and electronic devices that allow access to such areas shall occur according to
144 the hospital's policies and procedures.]
145
146 [(13)] (11) All variances, discrepancies, inconsistencies or non-compliance involving
147 controlled substances---including inventory, audits, security, record keeping, administration, and
148 disposal---shall be reported to the director of pharmacy services for review and investigation.
149 [Loss, diversion, abuse or misuse of medications shall be reported to the director of pharmacy
150 services, administration, and local, state and federal authorities as appropriate.]
151
152 [(14) The provision of pharmacy services in the event of a disaster, removal from use of
153 medications] (12) Medications subject to [product] recall [and reporting of manufacturer drug
154 problems shall occur according to the hospital's policies and procedures] shall be handled
155 through a medication recall program that includes removal of the product from patient
156 care and inventory sites, quarantine of the recalled product and maintenance of records.
157 Where the risk of harm is significant, patients receiving the medication and the prescriber
158 or authorizing practitioner shall be notified.
159
160 [(15)] (13) Compounding and repackaging of sterile and non-sterile medications in the
161 pharmacy shall be [done by pharmacy personnel] performed under the supervision of a
162 pharmacist. [Those] Compounded medications shall be labeled with the medication name[,];
163 strength[,]; lot number, as appropriate; [expiration] beyond use date; and other pertinent
164 information. [Record keeping] Records shall be maintained and quality control, including end-
165 product testing, shall be performed when appropriate [,shall occur according to the hospital's
166 policies and procedures].
167
168 [(16)] (14) [Compounding, repackaging or relabeling of] The director of pharmacy services
169 shall determine when non-pharmacy personnel may compound, repackage, or re-label
170 sterile and non-sterile medications [by non-pharmacy personnel shall occur according to the
171 hospital's policies and procedures. Medications] Except in approved circumstances,
172 medications compounded by non-pharmacy personnel shall be administered routinely by the
173 person who prepared them[,] and preparation shall occur just prior to administration [except in
174 circumstances approved by the director of pharmacy, nursing and administration. Compounded
175 sterile medications for parenteral administration prepared by non-pharmacy personnel shall not
176 be administered beyond twenty-four (24) hours of preparation.] Labeling shall include the
177 patient's name[, where] when appropriate, medication name, strength, beyond use date when
178 appropriate, identity of the person preparing and other pertinent information.
179
180 [(17)] (15) Compounded sterile medications shall be [routinely] prepared [in a suitably
181 segregated area in a Class 100 environment by pharmacy personnel. Preparation by
182 nonpharmacy personnel shall occur only in specific areas or in situations when immediate
183 preparation is necessary and pharmacy personnel are unavailable and shall occur according to
184 policies and procedures. All compounded cytotoxic/hazardous medications shall be prepared in

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

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

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

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

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

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

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

209
210 (16) For hazardous medications, a multidisciplinary team, including the director of
211 pharmacy services or his or her designee, shall ensure appropriate procedures for
212 identification of hazardous sterile and non-sterile medications, training of personnel,
213 storage and handling, facilities, equipment, apparel, preparation, packaging, labeling,
214 transport and handling outside the pharmacy, administering, cleanup of spills, and
215 disposal of medication waste and contaminated materials.

216
217 [(18)] (17) Radiopharmaceuticals shall be acquired, stored, handled, prepared, packaged,
218 labeled, distributed, administered and disposed of [according to the hospital's policies and
219 procedures and] only by or under the supervision of [personnel who are certified by the] a
220 pharmacist or physician who is a Nuclear Regulatory Commission (NRC) authorized user.
221 The NRC authorized supervising pharmacist or physician shall consult with the director of
222 pharmacy to ensure that radiopharmaceuticals are used consistent with the provisions of
223 this rule while recognizing the requirements for physically handling radiopharmaceuticals
224 only by NRC authorized personnel.

225
226 [(19)] (18) A medication profile record shall be maintained for each patient.

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

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

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

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

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

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

242 1. In an urgent situation;

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

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

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

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

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

260 [(22)] (19) The medication distribution system shall provide safety and accountability for all
261 medications, include unit of use and ready to administer packaging, and meet current standards
262 of practice. Distribution systems may include, but are not limited to, traditional unit dose
263 systems and electronic automated systems.

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

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

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

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

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

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

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

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

290
291 [(23)] (20) To prevent unnecessary entry to the pharmacy, a locked supply of routinely used
292 medications shall be available for access by authorized personnel when the pharmacist is
293 unavailable. Removal of medications from the pharmacy by ~~trained~~-authorized [*supervisory*]
294 nursing personnel, documentation of medications removed, restricted and unrestricted
295 medication removal, later review of medication orders by the pharmacist, and documented audits
296 of medications [*removal*] removed shall occur according to the hospital's policies and
297 procedures. [*The nurse shall remove only amounts necessary for administering until the*
298 *pharmacist is available.*]

299
300 [(24)] (21) Floor stock medications are medications that are not dispensed from the
301 pharmacy for a specific patient or do not require pharmacist prospective order
302 review/approval. Floor stock medications shall be limited to approved emergency and
303 nonemergency medications [*which are authorized by the director of pharmacy services in*
304 *conjunction with nursing and administration. The criteria, utilization and monitoring of*
305 *emergency and non-emergency floor stock medications shall occur according to the hospital's*
306 *policies and procedures*]. Supplies of emergency medications shall be available in designated
307 areas. Non-emergency floor stock medications shall be available only in limited quantities
308 as determined by the director of pharmacy.

309
310 [(25)] (22) All medication storage areas in the hospital shall be inspected at least monthly by a
311 pharmacist or [~~his or her designee, according to the hospital's policies and procedures~~]
312 ~~pharmacy technician~~. Expired, mislabeled or otherwise unusable medications shall not be
313 available for patient use.

314
315 [(26)] (23) The pharmacist shall be responsible for the acquisition, inventory control,
316 dispensing, distribution and related documentation requirements of investigational medications
317 [*according to the hospital's policies and procedures*]. A copy of the investigational protocol
318 shall be available [*in the pharmacy*] to all health care providers who prescribe [*or*], administer,
319 or dispense investigational medications. The identity of all recipients of investigational
320 medications shall be readily retrievable.

321

322 [(27)] (24) Sample medications shall be received and distributed only by the pharmacy
323 [according to the hospital's policies and procedures].
324

325 [(28)] (25) Dispensing of medications by the pharmacist [to] for use by patients [who are
326 discharged from the hospital or who are outpatients] outside of the hospital shall be in
327 compliance with [4 CSR 220] Chapter 338, RSMo, and 20 CSR 2220.
328

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

390
391 (27) Medications may be distributed from the pharmacy to locations outside the primary
392 hospital facility under the same procedures used for distribution within the primary
393 hospital facility when the remote location is part of the hospital licensed premises. Except
394 as otherwise authorized by section 338.165.6, RSMo, ~~Other~~ distributions to locations
395 outside the hospital shall be according to Missouri Board of Pharmacy drug distribution
396 requirements under 20 CSR 2220-5.020. All controlled substances shall be distributed
397 according to state and federal controlled substance law.

398
399 (28) Disposal of medication waste shall be according to 19 CSR 30-20.114 Environmental
400 Waste Management and Support Services.

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

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

405
406 [(30)] (29) Current medication information resources shall be [*maintained*] accessible in the
407 pharmacy and patient care areas. The pharmacist shall provide medication information to the
408 hospital staff as requested.

409
410 [(31)] (30) The director of pharmacy services or his or her pharmacist designee shall be an
411 active member of the pharmacy and therapeutics committee or its equivalent, which shall advise
412 the medical staff on all medication matters. A formulary shall be established which includes

413 medications based on an objective evaluation of their relative therapeutic merits, safety and cost
414 and shall be reviewed and revised on a continual basis.

415
416 (31) A medication use evaluation program shall be established which evaluates the use of
417 selected medications to ensure that they are used appropriately, safely and effectively. Follow-up
418 educational information shall be provided and appropriate interventions implemented if needed
419 in response to evaluation findings.

420
421 (32) The pharmacist shall be available to *[participate]* consult with medical and nursing staff
422 *[regarding decisions about]* to ensure appropriate medication use for individual patients,
423 including but not limited to: *[not to use medication therapy;]* medication selection, dosages,
424 routes and methods of administration; medication therapy monitoring; provision of medication-
425 related information; and counseling to individual patients. *[The pharmacist or designee shall*
426 *personally offer to provide medication counseling when discharge or outpatient prescriptions*
427 *are filled. The pharmacist shall provide requested counseling.]*

428
429 (33) *[Medication orders]* Medications shall be *[initiated or modified]* ordered only by
430 practitioners who have independent statutory authority to prescribe or who are *[legally given*
431 *authority]* authorized to order medications by their professional licensing agency as provided
432 by state law. *[That authority may be given through an arrangement with a practitioner who has*
433 *independent statutory authority to prescribe and who is a medical staff member. The]*

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

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

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

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

450 _____ 1

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

466 (A) The hospital shall:

- 467 1. Establish that such orders and protocols have been reviewed and approved by the
468 medical staff in consultation with the hospital's nursing and pharmacy leadership;
- 469 2. Demonstrate that such orders and protocols are consistent with nationally recognized
470 and evidence-based guidelines;
- 471 3. Ensure that the periodic and regular review of such orders and protocols is
472 conducted by the medical staff, in consultation with the hospital's nursing and pharmacy
473 leadership, to determine the continuing usefulness and safety of the orders and protocols;
474 and
- 475 4. Ensure that such orders and protocols are dated, timed and authenticated promptly
476 in the patient's medical record by the ordering practitioner or another practitioner
477 responsible for the care of the patient and authorized to write orders by hospital policy in
478 accordance with state law.

479 (B) Such orders and protocols:

- 480 1. Shall describe the clinical conditions under which the order or protocol may be
481 initiated;
- 482 2. Shall include the qualifications and/or description of persons who are authorized to
483 initiate the order or protocol within their scope of practice;
- 484 3. Shall include the patient care areas and/or type of patients where the order or
485 protocol may be initiated; and
- 486 4. Shall be readily retrievable by all persons authorized to order or initiate the order
487 or protocol.

488
489 (35) *[Medication orders shall be written according to policies and procedures and those written*
490 *by persons who do not have independent statutory authority to prescribe shall be included in the*
491 *quality improvement program.] With the exception of approved standing orders and*
492 *protocols, and approved vaccines which may be administered according to policy of the*
493 *medical staff after an assessment of contraindications, medications shall be administered*
494 *only upon the order of a person authorized to prescribe or order medications.*

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

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

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

503 (D) Verbal orders shall be:

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

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

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

510 4. Received using a read back procedure; and

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

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

516
517 (36) Automatic stop orders for all medications shall be established and shall include a procedure
518 to notify the prescriber of an impending stop order. A maximum stop order shall be effective for
519 all medications which do not have a shorter stop order. [*Automatic stop orders are not required*
520 *when the pharmacist continuously monitors medications to ensure that they are not*
521 *inappropriately continued.*]

522
523 (37) Medications shall be administered only by [*persons*] practitioners who have statutory
524 authority to administer or persons who [*have*] are authorized by the medical staff and meet
525 the following:

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

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

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

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

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

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

535 3. Patient assessment and monitoring;

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

538 5. Cardiopulmonary resuscitation;

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

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

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

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

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

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

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

560
561 (38) Medications *[brought to the hospital by patients]* in the possession of the patient at time
562 of admission shall be *[handled according to policies and procedures]* given to the patient's
563 representative unless there is an identified need to retain them.

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

567 (B) Controlled substances

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

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

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

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

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

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

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

600
601 *[(40) Medication incidents, including medication errors shall be reported to the prescriber and*
602 *the appropriate manager. Medication incidents shall be reported to the appropriate committee.*
603 *Adverse medication reactions shall be reported to the prescriber and the director of the*
604 *pharmacy services. The medication administered and medication reaction shall be recorded in*
605 *the patient's medical record. Adverse medication reactions shall be reviewed by the pharmacy*
606 *and therapeutics committee, and other medical or administrative committees when appropriate.]*
607

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

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

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

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

622

623