

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

**January 11, 2016**

The Missouri Hospital Advisory Committee met in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed. The meeting was called to order by Chairman Bert McClary at 10:02 a.m. on January 11, 2016.

**Committee Members Present**

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

**Staff Present**

Kimberly Grinston, Executive Director

**Others Present**

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

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

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

**James Gray – yes**

**Neil Schmidt- yes**

**Greg Teale – yes**

**Daniel Good – yes**

**Kevin Kinkade - abstain**

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

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

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

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

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

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

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

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

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

James Gray – yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Kevin Kinkade - yes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**MOTION TO ADJOURN**

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

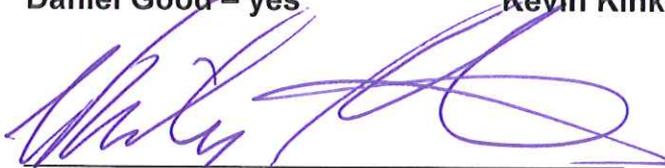
James Gray – yes

Neil Schmidt- yes

Greg Teale – yes

Daniel Good – yes

Kevin Kinkade - yes



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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

Date Approved: 05/06/2016

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 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 [(11)] (10) Controlled [substance storage areas in the pharmacy] substances shall be  
134 [separately] stored in locked [and] compartments separate from non-controlled substances.  
135 Controlled substances in the pharmacy shall be accessible only to authorized pharmacy staff.  
136 [Reserve supplies of all controlled substances in the pharmacy shall be locked.] Controlled  
137 [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, repackage 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~~ distributions to locations  
396 outside the hospital shall be according to Missouri Board of Pharmacy drug distribution  
397 requirements under 20 CSR 2220-5.020. All controlled substances shall be distributed  
398 according to state and federal controlled substance law.

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

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

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

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

410

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

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

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

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

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

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

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

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

451 | \_\_\_\_\_ )

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

467 (A) The hospital shall:

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

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

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

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

480 (B) Such orders and protocols:

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

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

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

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

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

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

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

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

504 (D) Verbal orders shall be:

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

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

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

511 4. Received using a read back procedure; and

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

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

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

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

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

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

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

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

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

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

536 3. Patient assessment and monitoring;

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

539 5. Cardiopulmonary resuscitation;

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

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

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

547 (F) *[A person who has statutory authority to administer shall be readily available at the time of*  
548 *administration. Training for persons who do not have statutory authority to administer shall be*  
549 *documented and administration]* Administration by *[those]* persons who do not have statutory  
550 authority to administer shall be included in the quality improvement program. *[Medications*  
551 *shall be administered 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 refilled 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.

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

(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

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.*