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 L. 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 L. 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 L. 581. General consensus to add “in accordance with the hospital’s policies and procedures” at the end of L. 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), L 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 24th 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 Neill Schmidt- yes Greg Teale – yes
Daniel Good – yes Kevin Kinkade - yes

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved: 05/06/2016
PROPOSED AMENDMENT

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

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

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

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

(A) Evaluating, selecting, and acquiring medications;
(B) Access to and security of the pharmacy and all other medication storage areas;
(C) Loss, diversion, abuse or misuse of controlled substances;
(D) Inspecting medication storage areas;
(E) Compounding, labeling, and re packaging of sterile and non-sterile medications;
(F) Hazardous medications;
(G) Investigational medications;
(H) Sample medications;
(I) Medications subject to recall;
(J) Patient medication orders;
(K) Variable time and/or frequency medication orders;
(L) Administering medications;
(M) Bedside medications;
(N) Medications in possession of the patient at the time of admission;
(O) Disposal of medications and medication waste;
(P) Reporting medication product problems; and
(Q) Providing medications for use outside the hospital.

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

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

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

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

(7) Medication storage areas outside of the pharmacy shall have proper conditions of sanitation, temperature, light, moisture, ventilation, and segregation and security. Refrigerated medications shall be stored in a [sealed compartment] separate [from food and laboratory materials] refrigerators. The director of pharmacy may approve storage of additional non-food items.

(B) Medication storage areas, including refrigerators, shall be accessible only to authorized personnel and locked [when appropriate] or secure.
1. Medication storage in patient care areas shall be considered secure if located within a locked storage compartment or within a separate closed room in an area that is staffed by nursing personnel authorized hospital personnel at all times.

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

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

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

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

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

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

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

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

[11] Controlled [substance storage areas in the pharmacy] substances shall be [separately] stored in locked [and] compartments separate from non-controlled substances. Controlled substances in the pharmacy shall be accessible only to authorized pharmacy staff. Reserve supplies of all controlled substances in the pharmacy shall be locked.] Controlled [substance storage areas] substances outside the pharmacy shall be [separately locked and]
accessible only to persons authorized to administer [them] controlled substances and to authorized pharmacy staff.

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

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

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

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

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

[(17)] (15) Compounded sterile medications shall be [routinely] prepared [in a suitably segregated area in a Class 10C environment by pharmacy personnel. Preparation by non-pharmacy personnel shall occur only in specific areas or in situations when immediate]
preparation is necessary and pharmacy personnel are unavailable and shall occur according to
policies and procedures. All compounded cytotoxic/hazardous medications shall be prepared in
a suitably segregated area in a Class II biological safety cabinet or vertical airflow hood. The
preparation, handling, administration and disposal of sterile or cytotoxic/hazardous medications
shall occur according to policies and procedures including: orientation and training of
personnel, aseptic technique, equipment, operating requirements, environmental considerations,
attire, preparation of parenteral medications, preparation of cytotoxic/hazardous medications,
access to emergency spill supplies, special procedures/products, sterilization, extemporaneous
preparations and quality control, handled, administered and disposed of according to
sections (17) and (28) of this rule and as follows:
(A) The director of pharmacy services shall ensure compliance with USP 31, General
Chapter <797> Pharmaceutical Compounding—Sterile Preparations, revised June 2008,
published by The United States Pharmacopeial Convention, 12601 Twinbrook Parkway,
Rockville, Maryland 20852.
(B) Compounded sterile medications shall be prepared in the pharmacy and only by
pharmacy personnel except as follows:
1. When prepared for immediate use as defined by USP 31, General Chapter <797>
Pharmaceutical Compounding—Sterile Preparations, revised June 2008, which is
incorporated by reference in this rule and is published by the United States Pharmacopeial
Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852. This rule does not
incorporate any subsequent amendments or additions.
2. When prepared in specific areas or situations when immediate preparation is
necessary and pharmacy services are not available, and only by persons who have
demonstrated competency in preparation of compounded sterile medications;
(C) Non-pharmacy personnel using a clean air workbench or isolator primary engineering
control shall be trained in proper techniques of use.

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

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

(19) A medication profile record shall be maintained for each patient.
(A) A medication profile record shall be maintained [and reviewed] by the pharmacist, or
may be shared by nursing and pharmacy.
1. Entries to a pharmacy medication profile record shall be made only by the
prescriber, a pharmacist, or a pharmacy technician. Each entry by a non-pharmacist shall
be reviewed and approved by the pharmacist prior to administering, except as allowed in
subsection (C) of this section.

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

(B) The pharmacist shall review the medication profile upon receiving a new medication
order prior to dispensing the medication. The pharmacist shall review the original, [prescriber’s
order or] a direct copy, or a visual image of the order.

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

1. In an urgent situation;
2. When the pharmacist is [unavailable, in which case] not available. When the
pharmacist is not available the order shall be reviewed within seventy-two (72) hours;
3. When the ordering, preparing, and administration is under the control supervision of
a practitioner authorized to order medications.

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

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

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

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

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

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

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

(D) All medications dispensed for a specific patient shall be labeled with the patient name,
medication name, strength, beyond use date and other pertinent information.
(E) Patient medications may be received from an outside contracted medication provider in accordance with applicable Board of Pharmacy regulations and other provisions of this rule. (F) Patient medications may be received from an authorized outside provider that is not a contracted medication provider. The medications shall:
1. Not be administered unless ordered by an authorized practitioner;
2. Be delivered directly to the pharmacy and not to a patient care area unless the pharmacist is not available; and
3. Be identified, determined suitable for use and documented by the pharmacist, or by an authorized practitioner when the pharmacist is not available, in which case the pharmacist shall also identify the medications within seventy-two (72) hours.
(G) The pharmacy may compound, repackage or re-label medications received from an outside provider, including prescriptions dispensed by a pharmacy, as necessary for proper distribution and administration. Records of compounding, repackaging or relabeling of prescriptions dispensed by a pharmacy shall allow identification of the original prescription.

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

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

[(25)] (22) All medication storage areas in the hospital shall be inspected at least monthly by a pharmacist or his or her designee, according to the hospital’s policies and procedures. Pharmacy technicians. Expired, mislabeled or otherwise unusable medications shall not be available for patient use.

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

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

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

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

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

1. Medications shall be provided according to the hospital's policies and procedures, including:
   a. circumstances when medications may be provided[;];
   b. practitioners authorized to order[;];
   c. specific medications [and];
   d. limited quantities[;];
   e. prepackaging and labeling by the pharmacist[;];
   f. final labeling to facilitate correct administration[;];
   g. delivery[;];
   h. counseling; and
   i. a transaction record.

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

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

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

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

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

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

(B) Automated dispensing systems may be used in accordance with all requirements of this section.
1. When the automated dispensing system is controlled by the prescriber it may be used only during times when no pharmacy services are reasonably available, except as allowed in paragraph (A)(6) of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[(30)] (29) Current medication information resources shall be [maintained] accessible in the pharmacy and patient care areas. The pharmacist shall provide medication information to the hospital staff as requested.
The director of pharmacy services or his or her pharmacist designee shall be an active member of the pharmacy and therapeutics committee or its equivalent, which shall advise the medical staff on all medication matters. A formulary shall be established which includes medications based on an objective evaluation of their relative therapeutic merits, safety and cost and shall be reviewed and revised on a continual basis.

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

The pharmacist shall be available to consult with medical and nursing staff regarding decisions about to ensure appropriate medication use for individual patients, including but not limited to: not to use medication therapy; medication selection, dosages, routes and methods of administration; medication therapy monitoring; provision of medication-related information; and counseling to individual patients. The pharmacist or designee shall personally offer to provide medication counseling when discharge or outpatient prescriptions are filled. The pharmacist shall provide requested counseling.

Medications shall be ordered only by practitioners who have independent statutory authority to prescribe or who are authorized to order medications by their professional licensing agency as provided by state law. That authority may be given through an arrangement with a practitioner who has independent statutory authority to prescribe and who is a medical staff member. The authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law. Such authority may include collaborative practice agreements, protocols or standing orders and shall not exceed the practitioner’s scope of practice. Practitioners given this authority of the non-physician practitioner. The hospital shall grant appropriate privileges to such non-physician practitioners.

Persons who are not hospital employees and who are granted authority to order medications through non-hospital based agreements shall be approved through the hospital credentialing process. When hospital-based agreements, protocols or standing orders are used, they shall be approved by the pharmacy and therapeutics or equivalent committee and granted appropriate privileges.

Pharmacist medication therapy services protocols shall:

1. Be authorized pursuant to a document granting hospital privileges to the pharmacist which is signed by the pharmacist;
2. Include the minimum education, training and other qualifications that must be met by the pharmacist; and
3. Be approved by the medical staff.
(34) [All medication orders shall be written in the medical record and signed by the ordering practitioner with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician approved hospital policy/protocol after an assessment for contraindications. When medication therapy is based on a protocol or standing order and a specific medication order is not written, a signed copy of the protocol or of an abbreviated protocol containing the medication order parameters or of the standing order shall be placed in the medical record with the exception of physician approved policies/protocols for the administration of influenza and pneumococcal polysaccharide vaccines after an assessment for contraindications. The assessment for contraindications shall be dated and signed by the registered nurse performing the assessment and placed in the medical record. Telephone or verbal orders shall be accepted only by authorized staff, immediately written and identified as such in the medical record and signed by the ordering practitioner within a time frame defined by the medical staff.] Hospitals may use pre-printed and electronic standing orders, order sets and protocols for patient medication orders that are authorized to be initiated prior to receiving a patient medication order from an authorized practitioner.

(A) The hospital shall:

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

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

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

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

(B) Such orders and protocols:

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

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

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

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

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

(A) All medication orders shall be entered in the medical record by authorized individuals authorized to do so by hospital policy.
(B) Medication orders shall be signed by the ordering practitioner or authenticated by another practitioner who is responsible for the care of the patient as authorized by state or federal law.

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

(D) Verbal orders shall be:
   1. Discouraged and used only when it is impossible or impractical to write the order or enter it electronically without delaying treatment;
   2. Received only by persons who are authorized by the medical staff and authorized to administer or dispense the ordered medications within their scope of practice;
   3. Immediately entered, dated, timed, signed and identified as such in the medical record by the receiver;
   4. Received using a read back procedure; and
   5. Authenticated by an authorized practitioner within a timeframe defined by the medical staff.

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

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

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

   (A) Are at least 18 years of age;
   (B) Have a high school diploma or equivalent;
   (C) Have been trained in each pharmacological category of medication they administer, and administration shall be limited to the scope of their practice; and
   (D) Persons who do not have statutory authority to administer shall complete a training program approved by the hospital that includes:
      1. An introduction to human body systems and the effects of medications on them;
      2. The pharmacology of each drug to be administered, including dosing, interactions, adverse effects, allergies, incompatibilities and contraindications;
      3. Patient assessment and monitoring;
      4. Administration routes and techniques, including aseptic and parenteral administration techniques when parenteral medications will be administered;
      5. Cardiopulmonary resuscitation;
      6. Acquisition, storing, record keeping and security; and
      7. Education and clinical training that includes a written and practical examination to demonstrate competency.
(E) Persons who do not have statutory authority to administer medications shall not administer
parenteral medications, controlled substances or medications that require professional assessment
by a licensed practitioner at the time of administration unless a practitioner who has
statutory authority to administer is immediately available at the time of administration.
(F) A person who has statutory authority to administer shall be readily available at the time of
administration. Training for persons who do not have statutory authority to administer shall be
documented and administered. Administration by [those] persons who do not have statutory
authority to administer shall be included in the quality improvement program. [Medications
shall be administered only upon the order of a person authorized to prescribe or order
medications. Administration by all persons shall occur according to the hospital's policies and
procedures.]
(G) Health professions students in approved training programs may administer
medications under the supervision of their instructors.
(H) Each medication administered shall be documented in the patient's medical record
by the person who administered the medication.
(I) Medications shall be self-administered or administered by a patient's representative
only upon the order of the prescriber. A nurse shall confirm that administration has
occurred and shall document such in the patient’s medical record.

(38) Medications [brought to the hospital by patients] in the possession of the patient at time
of admission shall be [handled according to policies and procedures] given to the patient's
representative unless there is an identified need to retain them.
(A) Medications that are not given to the patient's representative and that are not to be
administered shall be documented, sealed and stored in a locked area accessible
only to individuals authorized to access medications.
(B) Controlled substances
1. Shall be inventoried at a minimum upon admission and discharge by a person
who is authorized to administer controlled substances or by authorized
pharmacy personnel and a copy of each inventory shall be provided to the
pharmacy;
2. Shall be security sealed and stored in a locked area accessible only to
individuals authorized to administer controlled substances or to authorized
pharmacy personnel; and
3. Inventory at the time of discharge shall include a receipt signature of the
patient or the patient's representative.
(C) [They] Medications shall not be administered unless so ordered by the prescriber and
positively identified, determined suitable for administration, and documented by the
pharmacist, or by the prescriber when the pharmacist is not available, in which case the
pharmacist shall also identify the medications within seventy-two (72) hours.
(D) Medications in the legal possession of the patient shall be returned to the patient or
the patient's representative at the time of discharge except when the patient has expired in
accordance with the hospital's policies and procedures. When medications are not
returned to the patient or the patient's representative, they shall be transferred to the
pharmacy, documented and destroyed. Controlled substances shall be inventoried and
destroyed by two (2) authorized pharmacy personnel or as otherwise authorized by law.
(39) [Medications shall be self-administered or administered by a responsible party only upon the order of the prescriber and according to policies and procedures.] The hospital shall implement a medication safety program to prevent adverse medication events, including medication errors, adverse medication reactions and medication incompatibilities. The program shall:

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

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

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

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

AUTHORITY: sections 192.016 and 197.080[,] RSMo 2000 and 197.154, RSMo Supp. 2007


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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed amendment with the Missouri Department of Health and Senior Services, Division of Regulation and Licensure, Jeanne Serra, Division Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.
Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220—State Board of Pharmacy Chapter 6—Pharmaceutical Care Standards

20 CSR 2220-6.040 Administration by Medical Prescription Order

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

(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.

(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 (2)(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.

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

(C) Successfully complete a certificate program in the administration of drugs accredited provided by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy. (1) a continuing education provider accredited by the Accreditation Council for Pharmacy Education (ACPE) or (2) a governmental entity, healthcare professional organization or 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:

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 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.

(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 the 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 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.

Comment [SK2]: The Advisory Committee suggested the rule should also allow offsite storage. KIM QUESTION: Was this suggested for all entities 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.

(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.
