

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

PROPOSED RULE

19 CSR 30-20.100 Pharmacy Services and Medication Management.

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) There shall be evidence of the education, training, experience, and demonstrated competency for all duties assigned in the pharmacy technicians' personnel records.

(2) In addition to other authorized duties, a pharmacy technician may perform the following duties:

(A) Verify the final product prepared by another pharmacy technician when a pharmacist is present for purposes of distributing medication within the hospital for subsequent administration by hospital staff authorized to administer medication, provided the final product is verified by authorized hospital staff prior to administration.

1. The pharmacy technician shall have a current certificate issued by the Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians or their successor organizations.

2. The pharmacy technician shall have completed training and documented competency in final product verification as attested by the director of pharmacy.

3. A pharmacy technician shall not be authorized to verify the final product of compounded medications or the repackaging activities of another pharmacy technician.

(B) Perform assigned duties under visual and auditory supervision of a pharmacist at a different site, including, technology assisted final product verification. Documentation of electronic final product verification shall be maintained at the dispensing site.

1. The pharmacy technician shall have a current certificate issued by the Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians or their successor organizations.

2. The pharmacy technician shall have completed training and documented competency in the assigned responsibilities being performed remotely as attested by the director of pharmacy.

3. The director of pharmacy is responsible for developing and implementing standards to ensure adequate supervision of electronically supervised technicians.

(3) An intern pharmacist licensed by the Board of Pharmacy may also perform any activity authorized for pharmacy technicians pursuant to this rule.

(4) Persons involved in compounding, repackaging, dispensing, 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.

(5) 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.

(6) Patient medications may be received from an authorized provider. The medications shall:

(A) Be delivered directly to the pharmacy and not to a patient care area unless the pharmacist is not available.

(B) When a pharmacist is present, be identified, determined suitable for use and documented by the pharmacist. When a pharmacist is not present, be identified and documented by an authorized practitioner. Unused doses of medication shall be identified by the pharmacist when the pharmacist is present.

(C) 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.

(7) Sample medications, if allowed, shall be received and distributed only by the pharmacy.

(8) Medications may be provided to patients for use outside the hospital, by persons other than the pharmacist.

(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;
 - 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 that is reasonably accessible to the patient;

4. The medication provided shall be limited to urgently needed treatment;

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 a pharmacist, 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 a pharmacy according to regulations of the Missouri Board of Pharmacy, including, but not limited to 20 CSR 2220-2.900.

(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. Written instructions for use shall be provided by a pharmacist, prescriber or registered nurse at the time of discharge.

3. Controlled substances shall not be sent with the patient, except that controlled substance infusions or continuous delivery systems currently connected to the patient may be sent as follows:

a. The medication is necessary for administration during transport of the patient; and

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

(9) The director of pharmacy services or his/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.

(10) 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. Authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law

(11) Medications in the possession of the patient at time of admission shall be 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 shall be security sealed and stored in a locked area accessible only to individuals authorized to administer controlled substances or to authorized pharmacy personnel.

AUTHORITY: section[s] 192.006[and 197.080], RSMo [2000] 2016 [and 197.154, RSMo Supp. 2007] and section 197.080, RSMo Supp. 2018. This rule previously filed as 19 CSR 30-20.021(3)(G). Original rule filed June 27, 2007, effective Feb. 29, 2008. *Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed amendment with the Missouri Department of Health and Senior Services, Division of Regulation and Licensure, Dean Linneman, 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.