REVISED MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

March 21, 2018
3:30 p.m.

Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 3:30 p.m. on March 21, 2018 via conference call. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3550 Amazonas Drive, Jefferson City, Missouri at 3:30 p.m. on March 21, 2018.

***PUBLIC PARTICIPANTS MAY ALSO JOIN THE CALL BY CALLING: (573) 526-5402. PLEASE MUTE YOUR PHONE IF JOINING THE CALL. PUBLIC PARTICIPATION MAY BE LIMITED DUE TO TIME RESTRICTIONS. QUESTIONS/COMMENTS DURING THE CALL SHOULD BE E-MAILED TO: JENNIFER.LUEBBERT@PR.MO.GOV***

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes pursuant to Section 610.021(1), (13) and (14) and section 324.001.8, RSMo. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.
REVISED MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

March 21, 2018
3:30 p.m.

OPEN SESSION AGENDA

1. Call to Order: Christian Tadrus, PharmD, President
2. Roll Call
3. Review of SB 1068/Proposed Pharmacy Technician Activity Language
4. Review of proposed 19 CSR 30-20.100.2 & Technician Expanded Activity Language
5. Future Meeting Dates/Times
6. The Board may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (5), (7), and (14) and under Section 324.001.8, and .9 RSMo. The Board will return to open session at the conclusion of discussion on closed session items.
7. Adjournment
SECOND REGULAR SESSION

SENATE BILL NO. 1068

99TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Read 1st time February 28, 2018, and ordered printed.

ADRIANE D. CROUSE, Secretary.

67068.011

AN ACT

To amend chapter 197, RSMo, by adding thereto one new section relating to pharmacy technicians.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapter 197, RSMo, is amended by adding thereto one new section, to be known as section 197.710, to read as follows:

197.710. 1. In addition to other services authorized by law or regulation, a pharmacy technician may perform the functions described in this section if he or she is registered as a pharmacy technician under section 338.013 and the technician complies with all of the requirements of this section, as applicable to the function being performed.

2. Such functions performed under this section shall only be performed in a setting where the delivery of hospital pharmaceutical services is subject to regulation under sections 197.010 to 197.120.

3. A pharmacy technician may verify the final product of another pharmacy technician in order to ensure an accurate and timely supply of pharmaceuticals if the pharmacy technician has:

   (1) A valid certificate issued by the national Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians, or their successor organizations; and

   (2) Documented competency in final product verification as attested to by the director of the pharmacy.

4. A pharmacy technician shall not be authorized under this section to independently verify the accuracy of compounded or repackaged drugs that have not previously been verified by a pharmacist.
5. To act as a pharmacy technician under supervision by visual and auditory means by a licensed pharmacist at a different site, the pharmacy technician shall have:

   (1) A valid certificate issued by the national Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians, or their successor organizations; and

   (2) Documented competency in the assigned responsibilities being performed as attested to by the director of the pharmacy.

6. The director of the pharmacy shall be responsible for developing and implementing standards to ensure adequate supervision of pharmacy technicians at a different site.

7. An intern pharmacist licensed by the board of pharmacy under section 338.035 may also perform any activity authorized for pharmacy technicians under this section.

8. Nothing in this section shall be construed to modify the responsibility of the director of the pharmacy to ensure the safe provision of pharmaceutical services.
March 7, 2018

Richard Grindstaff, R.N.
Chief, Bureau of Hospital Standards
Section for Health Standards & Licensure
Department of Health and Senior Services
3418 Knipp Drive
Jefferson City, MO 65109-5701

Dear Richard:

Recently, Missouri Hospital Association learned of concerns voiced by the Missouri Board of Pharmacy regarding proposed draft regulations for 19 CSR 30-20.100 Pharmacy Services and Medication Management in Hospitals. Specifically, the board expressed concern with “bifurcation” of pharmacy technician roles in different practice settings as well as the “tech-check-tech” concept “absent a strong well-developed approach.” The board suggested DHSS do additional research before approving a regulatory approach. MHA obviously shares the board’s focus on safe patient care delivery; however, it strongly disagrees with the board’s position on the draft regulations regarding the role of pharmacy technicians in hospitals. MHA supports the draft regulations.

Today, the role of the pharmacy technician is significantly different in the hospital setting than in the retail setting. There already is a bifurcation of roles and corresponding orientation and education requirements. Hospitals, certified by the Centers for Medicare & Medicaid Services and licensed by the state, have stringent orientation and ongoing education requirements. Technicians in hospitals are providing services for a much sicker and more medically complex population and in an environment that cannot be compared to that of the retail setting. The fact that the board has been unsuccessful in addressing uniform standards for pharmacy technicians, which would increase their value by increasing their competency requirements, does not mean health care delivery in areas where medicine is progressing at a rapid pace must suffer. Patients are placed at greater risk of errors when allowed to be cared for by members of the health care team for which there are no standards. Hospitals have responded to their unique needs and ensured the unique responsibilities of working in a hospital are addressed. We have all types of professions working in different settings with different levels of responsibility.

The board itself has proposed language to allow for an expanded scope of practice among pharmacy technicians. The intent of their language was to create levels of pharmacy technicians and address uniform education requirements as well as advance the technicians’ roles through remote verification and tech-check-tech activities. Instead of proposing to hold the department
and hospitals back, a truly collaborative approach would be to offer suggested additional language that would address specific concerns regarding the process of tech-check-tech. The department and the board have the power to promulgate rules together. MHA is committed to working with the department as well as the board to create sample best practice policies and procedures. In addition, hospitals have robust quality assurance programs that include pharmacy services and serve as a reliable platform for monitoring of program effectiveness. An article published in *Pharmacy Times* in June 2015 suggests:

>“Tech-check-tech (TCT) programs are authorized by pharmacy Boards in at least 9 states. A metaanalysis of 11 studies published since 1978 shows that technicians have comparable accuracy to pharmacists in performing final checks when restocking automated medication dispensing systems.”

>“The University of Wisconsin Hospital and Clinics implemented a TCT program and recorded a >99.8% accuracy rate for technicians filling unit-dose medication cassettes.”

>“TCT programs are generally limited to the institutional setting and require advanced education and training requirements.”

Thank you for the opportunity to comment. If you have any questions or concerns, please contact me at swillson@mhanet.com or 573/893-3700, ext. 1304.

Sincerely,

Sarah Willson
Vice President of Clinical and Regulatory Affairs

sw/pt

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

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) 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; and

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 and electronic supervision of a pharmacist at a remote different site, including, 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, and;

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 outside provider. The medications shall:

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

   (B) When a pharmacist is present, medication shall be identified, determined suitable for use and documented by the pharmacist. When a pharmacist is not present, medication shall 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 [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 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.


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.