Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

February 1, 2018
10:00 a.m.
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

Notice is hereby given that the Missouri Board of Pharmacy’s Hospital Advisory Committee will be meeting at 10:00 a.m. on February 1, 2018. A tentative agenda is attached. If any member of the public wishes to attend the meeting by participating in the conference call, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 10:00 a.m. on February 1, 2018.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy’s Hospital Advisory Committee is authorized to close meetings, records and votes pursuant to Section 610.021(1). The Committee may go into closed session at any time during the meeting. 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.

Please see the attached tentative agenda for this meeting.
TENTATIVE AGENDA
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

February 1, 2018
10:00 a.m.
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

1. Welcome & Introductions
2. Approval of Minutes
   a. November 14, 2017
   b. December 6, 2017
   c. December 14, 2017
3. Board Updates
4. DHSS Updates
5. Missouri Hospital Association Updates
6. DHSS/SB 501 Hospital Rule Review Update
7. 2018 Proposed Legislation
   a. Pharmacy Related Legislation Watch List
   b. HB 1870
   c. Pharmacy Practice Advancement Legislation
   d. Pharmacy Technician Legislation
8. Missouri Pharmacy Practice Guide Revision Affecting Class-B Hospitals
9. Review of Committee Operations/Strategic Planning
   a. Membership Tenure
   b. Meeting Frequency/Format
   c. Scope of Authority/Committee Review
   d. Future Meeting Topics
10. Bd. of Pharmacy Automated Distribution Rule Discussion
11. Future Meeting Dates
12. Public Questions/Comments
13. Adjournment
OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting
November 14, 2017
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, Missouri 65109

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.

**Committee Members Present**
Greg Teale, R.Ph., Chairman
Daniel Good, R.Ph., Member
James Gray, R.Ph., Member (via phone)
Bert McClary, R.Ph., Member
David Wolfrath, R.Ph., Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector
Christa Nilges, Senior Office Support Assistant

**Others Present**
Sarah Willson, Missouri Hospital Association
Nathan Hanson, Truman Medical Center
Richard Grindstaff, Missouri Dept. of Health and Senior Services
Kristen Repp, Mercy Hospital
Kathie Thomas, Missouri Depart. of Health and Senior Services

Chairman Teale opened the meeting at approximately 10:04 a.m. and roll-call was taken.

**Agenda Item # 2 (Approval of Minutes):** The August 7, 2017, minutes were presented for approval. A motion was made by David Wolfrath, seconded by Bert McClary, to approve the August 7, 2017, minutes. The motion passed 3:0:0:3 with roll call vote as follows:

James Gray – yes  
Colby Grove- absent  
Kevin Kinkade – absent  
Bert McClary – yes  
Daniel Good – absent  
David Wolfrath- yes
A motion was made by Bert McClary, seconded by James Gray, to approve the October 12, 2017, minutes. The motion passed 3:0:0:3 with roll call vote as follows:

James Gray – yes  Colby Grove- absent  Daniel Good – absent  
Kevin Kinkade – absent  Bert McClary – yes  David Wolfrath- yes

**Agenda Item # 3 (Board of Pharmacy Updates):** Kimberly Grinston reported the proposed administration by medical prescription order rule amendment would be returned to the board to discuss mandatory VAERS reporting along with the immunization by protocol rule.

**Agenda Item # 4 (Department of Health Updates):** Kathie Thomas reported DHSS has been working with the Missouri Hospital Association to conduct the mandatory rule review required by SB 501. Sarah Willson indicated DHSS is under a very tight timeline and noted the Missouri Hospital Association would be submitting final comments to DHSS after the Hospital Advisory Committee's review/recommendations.

DANIEL GOOD JOINED THE MEETING AT 1:00 P.M. VIA CONFERENCE CALL.

**Agenda Item # 5 (Review/Crosswalk of Missouri Hospital Regulations and CMS Conditions of Participation):** The Committee met and discussed suggested revisions to 19 CSR 30-20.100. Committee suggestions/recommendations are included in Attachment A. Committee consensus to review final changes/recommendations at the next meeting.

Chairman Greg Teale asked about proposing new rule language that may assist hospitals in conjunction with the SB 501 rule review. Richard Grindstaff indicated the Governor’s office has asked agencies to decrease regulation and not add new requirements. Sarah Willson noted DHSS previously indicated that sensible rule language may be considered while the regulations are open for review. Greg Teale suggested proposing rule language to address remote supervision and tech-check-tech allowances. Additional Committee discussion held; Committee consensus to discuss further at the next Committee meeting.

**AGENDA ITEM # 13 (Future Meeting Dates/Topics)-** Committee discussion held on future meeting dates; Committee consensus to meet on December 6, 2017, from 8:00 – 10:00 a.m. Bert McClary suggested the Committee discuss/review additional DHSS rules that may impact hospital pharmacy such as DHSS rules addressing construction standards, long-term care, medical staff and vital records. Richard Grindstaff and Sarah Willson reported DHSS may be rescinding some of the rules referenced to comply with SB 501. Mr. McClary also expressed an interest in DHSS rules relating to writing orders, maintenance of medical records and critical access hospitals. Committee consensus to discuss further at the next meeting.
THE HOSPITAL ADVISORY COMMITTEE ADJOURNED BY CONSENSUS AT 3:02 P.M.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
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) 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. 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 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 policies and procedures for the selection, acquisition, storage, security, distribution,
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 repackaging 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) Sufficient professional and supportive personnel shall be available to ensure required services are provided. Pharmacists and pharmacist interns shall be currently licensed in Missouri. **TAG 493**

(3) 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 technicians shall be performed under the supervision of a pharmacist. Interpretation of medication orders by 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 maintain the safety of personnel and the security and stability of medications stored, handled and dispensed.

**Strike current 4**

(6) The pharmacy and its medication storage areas shall have proper conditions of sanitation, temperature, light, moisture, ventilation, 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 designated nursing personnel according to section (20) of this rule. **TAG 726, 747, 502, 503.**

(7) Medication storage areas outside of the pharmacy shall have proper conditions of sanitation, temperature, light, moisture, ventilation, segregation and security.
(A) Refrigerated medications shall be stored in a separate refrigerator. 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 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 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) Records shall be maintained of medication transactions, including: acquisition, compounding, repackaging, dispensing or other distribution, administration and controlled substance disposal. 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.

(9) The director of pharmacy services shall ensure the accountability of all controlled substances. Security and recordkeeping shall be in compliance with applicable provisions of 19 CSR 30-1. Inventories of controlled substances outside the pharmacy shall be reconciled as follows:

(A) When controlled substances are stored 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, inventories of Schedule II controlled substances shall be reconciled at each shift change and inventories of Schedule III–V controlled substances shall be reconciled at least daily; and

(C) Inventories of controlled substances in the pharmacy shall be reconciled at least monthly.

(10) Controlled substances shall be stored in locked compartments separate from non-controlled substances. Controlled substances in the pharmacy shall be accessible only to authorized pharmacy staff. Controlled substances outside the pharmacy shall be accessible only to persons authorized to administer controlled substances and to authorized pharmacy staff.
(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.

(12) Medications subject to recall 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 shall be notified.

(13) Compounding and repackaging of **sterile and non-sterile** medications in the pharmacy shall be performed under the supervision of a pharmacist. **Compounded** medications shall be labeled with the medication name; strength; lot number, **as appropriate; beyond use date; and other pertinent information. Records shall be maintained and quality control, including end-product testing, shall be performed when appropriate. **Tag 501.**

(14) The director of pharmacy services shall determine when non-pharmacy personnel may compound, repackage, or re-label **sterile and non-sterile** 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. Labeling shall include the patient’s name **when appropriate,** medication name, strength, beyond use date **when appropriate,** identity of the person preparing and other pertinent information. **TAG 405 & 501**

(15) Compounded **sterile medications** shall be prepared, 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, 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.

(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 shall be trained in proper techniques of use.

(16) For hazardous medications, a multidisciplinary team, including the director of pharmacy services, 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.

(17) Radiopharmaceuticals shall be acquired, stored, handled, prepared, packaged, labeled, distributed, administered and disposed of only by or under the supervision of 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.

(18) A medication profile shall be maintained for each patient.

(A) A medication profile shall be maintained by the pharmacist, or may be shared by nursing and pharmacy.

1. Entries to a pharmacy medication profile 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 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, 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 the pharmacist is:

1. In an urgent situation;
2. When the pharmacist is 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 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.
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.

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 nursing personnel, documentation of medications removed, restricted and unrestricted medication removal, later review of medication orders by the pharmacist, and documented audits of medications removed shall occur according to the hospital’s policies and procedures.

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 nonemergency medications. 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.

All medication storage areas in the hospital shall be inspected at least monthly by a pharmacist or pharmacy technician. Expired, mislabeled or otherwise unusable medications shall be removed.
medications shall not be available for patient use.

(23) The pharmacist shall be responsible for the acquisition, inventory control, dispensing, distribution and related documentation requirements of investigational medications. A copy of the investigational protocol shall be available to all health care providers who prescribe, administer, or dispense investigational medications. The identity of all recipients of investigational medications shall be readily retrievable.
(24) Sample medications, if allowed, shall be received and distributed only by the pharmacy.

(25) Dispensing of medications by the pharmacist for use by patients outside of the hospital shall be in compliance with 20 CSR 2220.

(26) 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 within a reasonable distance of the hospital that is reasonably accessible to the patient;

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

   5. Controlled substances shall not be sent with the patient, except that controlled substance infusions or continuous delivery systems 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; and

      (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. 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.

(29) Current medication information resources shall be accessible in the pharmacy and patient care areas. The pharmacist shall provide medication information to the hospital staff as requested.

(30) 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. 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.

(31) 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.

(32) The pharmacist shall be available to consult with medical and nursing staff to ensure appropriate medication use for individual patients, including but not limited to: medication selection, dosages, routes and methods of administration; medication therapy monitoring; provision of medication-related information; and counseling to individual patients.

(33) 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.

   (A) Authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law. Such authority shall not exceed the scope of practice of the non-physician practitioner. The hospital shall grant appropriate privileges to such non-physician practitioners.

   (B) 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 and granted appropriate privileges.

   (C) 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) 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) 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 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 time frame 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.

(37) Medications shall be administered only by practitioners who have statutory authority to administer or persons who 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 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) Administration by persons who do not have statutory authority to administer shall be included in the quality improvement program.

(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 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
   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) 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. 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.
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.


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.
The Missouri Hospital Advisory Committee met in open session via conference call during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed.

**Committee Members Present**
Greg Teale, R.Ph., Chairman  
Daniel Good, R.Ph., Member  
James Gray, R.Ph., Member  
Colby Grove, R.Ph., Member  
Kevin Kinkade, R.Ph., Member  
Bert McClary, R.Ph., Member  
David Wolfrath, R.Ph., Member

**Staff Present**
Christian Tadrus, Bd. of Pharmacy President  
Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector

**Others Present**
Ron Fitzwater, Missouri Pharmacy Association  
Nathan Hanson, Truman Medical Center  
Kathie Thomas, Missouri Depart. of Health and Senior Services  
Sarah Willson, Missouri Hospital Association

Chairman Teale opened the meeting at approximately 8:01 a.m. and roll-call was taken.

**Agenda Item # 2 (Board of Pharmacy Updates):** Kimberly Grinston reported no Board updates at this time.

**Agenda Item # 3 (Department of Health Updates):** Kathie Thomas reported no additional DHSS updates at this time.

**Agenda Item # 4 (SB 501 Review):** The Committee met and discussed suggested revisions to 19 CSR 30-20.100 from the November 14, 2017, meeting. Committee suggestions/recommendations are included in Attachment A. Committee consensus to review final changes/recommendations at the next meeting.
CHRISTIAN TADRUS AND KATHIE THOMAS LEFT THE CONFERENCE CALL AT APPROXIMATELY 9:00 A.M.

AGENDA ITEM # 5 (Section 338.013- Regulation of Missouri Pharmacy Technicians) - The Committee reviewed proposed rule/statutory language from the Missouri Hospital Association that would authorize remote pharmacy technician supervision and tech-check-tech activities. Sarah Willson indicated Committee suggestions would need to be submitted as soon as possible to meet DHSS rule review timelines; Kimberly Grinston reported the Board of Pharmacy would review the language on December 19, 2017.

Greg Teale suggested narrowing the language to only hospital settings under DHSS’ jurisdiction to avoid potential conflicts with Class-B and Class-H pharmacy regulatory requirements. Mr. Teale suggested remote technician supervision/tech-check-tech would significantly benefit Missouri hospitals and urged the Committee to avoid potential delays that might be caused by an expanded scope. Additional Committee discussion held on potential rule/statutory language. Committee suggestions are included in Attachment B; Committee consensus to finalize proposed suggestions at a future meeting.

Greg Teale asked if the Missouri Hospital Association intended to propose rule language to expand allowed medication therapy services and grant pharmacists controlled substance modification authority. Sarah Willson indicated she talked with BNDD and DEA representatives and believes a statutory change would be needed to fully address pharmacist controlled substance authority. Greg Teale suggested collaborating with the Missouri Pharmacy Association (MPA) to address the MT/controlled substance issues during the 2018 legislative session; Ron Fitzwater stated the MPA Board would be open to discussions.

AGENDA ITEM # 13 (Future Meeting Dates/Topics) - Committee discussion held on future meeting dates; Committee consensus to meet on December 14, 2017, via conference call to finalize suggested rule language.

THE HOSPITAL ADVISORY COMMITTEE ADJOURNED BY CONSENSUS AT 10:01 A.M.

______________________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:

Missouri Board of Pharmacy
Hospital Advisory Committee
Open Minutes
December 6, 2017
Page 2 of 2
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. 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 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 policies and procedures for the selection, acquisition, storage, security, distribution, 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 repackaging 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) **Sufficient** professional and supportive personnel shall be available to ensure required services are provided. Pharmacists and pharmacist interns shall be currently licensed in Missouri. TAG 493

(3) **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 technicians shall be performed under the supervision of a pharmacist. Interpretation of medication orders by 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 maintain the safety of personnel and the security and stability of medications stored, handled and dispensed.

**Strike current 4**

(6) The pharmacy and its medication storage areas shall have proper conditions of sanitation, temperature, light, moisture, ventilation, 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 designated nursing personnel according to section (20) of this rule. TAG 726, 747, 502, 503.

(7) Medication storage areas outside of the pharmacy shall have proper conditions of sanitation, temperature, light, moisture, ventilation, segregation and security.

(A) Refrigerated medications shall be stored in a separate refrigerator. 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 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 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) Records shall be maintained of medication transactions, including: acquisition, compounding, repackaging, dispensing or other distribution, administration and controlled substance disposal. 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.

(9) The director of pharmacy services shall ensure the accountability of all controlled substances. Security and recordkeeping shall be in compliance with applicable provisions of 19 CSR 30-1. Inventories of controlled substances outside the pharmacy shall be reconciled as follows:

(A) When controlled substances are stored 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, inventories of Schedule II controlled substances shall be reconciled at each shift change and inventories of Schedule III–V controlled substances shall be reconciled at least daily; and

(C) Inventories of controlled substances in the pharmacy shall be reconciled at least monthly.

(10) Controlled substances shall be stored in locked compartments separate from non-controlled substances. Controlled substances in the pharmacy shall be accessible only to authorized pharmacy staff. Controlled substances outside the pharmacy shall be accessible only to persons authorized to administer controlled substances and to authorized pharmacy staff.
(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.

(12) Medications subject to recall 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 shall be notified.

(13) Compounding and repackaging of sterile and non-sterile medications in the pharmacy shall be performed under the supervision of a pharmacist. **Compounded** medications shall be labeled with the medication name, strength, lot number, as appropriate; beyond use date; and other pertinent information. **Records shall be maintained** and quality control, including end-product testing, shall be performed when appropriate. **Tag 501**

(14) The director of pharmacy services shall determine when non-pharmacy personnel—may compound, repackage, or re-label sterile and non-sterile 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. Labeling shall include the patient’s name when appropriate, medication name, strength, beyond use date when appropriate, identity of the person preparing and other pertinent information. **TAG 405 & 501**

(15) Compounded sterile medications shall be prepared, 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, 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.

(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 shall be trained in proper techniques of use.

(16) For hazardous medications, a multidisciplinary team, including the director of pharmacy services, 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.

(17) Radiopharmaceuticals shall be acquired, stored, handled, prepared, packaged, labeled, distributed, administered and disposed of only by or under the supervision of 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.

(18) A medication profile shall be maintained for each patient. 
(A) A medication profile shall be maintained by the pharmacist, or may be shared by nursing and pharmacy.
   1. Entries to a pharmacy medication profile 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 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, a direct copy, or a visual image of the order.
(C) The pharmacist shall review a medication order prior to the administration of the initial dose, except the pharmacist is:
   1. In an urgent situation;
   2. When the pharmacist is 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 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.
(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. 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.

(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.

(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 nursing personnel, documentation of medications removed, restricted and unrestricted medication removal, later review of medication orders by the pharmacist, and documented audits of medications removed shall occur according to the hospital’s policies and procedures.

(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 nonemergency medications. 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.

(22) All medication storage areas in the hospital shall be inspected at least monthly by a pharmacist or pharmacy technician. Expired, mislabeled or otherwise unusable medications shall not be available for patient use.

(23) The pharmacist shall be responsible for the acquisition, inventory control, dispensing, distribution and related documentation requirements of investigational medications. A copy of the investigational protocol shall be available to all health care providers who prescribe, administer, or dispense investigational medications. The identity of all recipients of investigational medications shall be readily retrievable.
(24) Sample medications, if allowed, shall be received and distributed only by the pharmacy.

(25) Dispensing of medications by the pharmacist for use by patients outside of the hospital shall be in compliance with 20 CSR 2220.

(26) 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 within a reasonable distance of the hospital that is reasonably accessible to the patient;

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

5. Controlled substances shall not be sent with the patient, except that controlled substance infusions or continuous delivery systems 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; and

(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. 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.

(29) Current medication information resources shall be accessible in the pharmacy and patient care areas. The pharmacist shall provide medication information to the hospital staff as requested.

(30) 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. 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.

(31) 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.

(32) The pharmacist shall be available to consult with medical and nursing staff to ensure appropriate medication use for individual patients, including but not limited to: medication selection, dosages, routes and methods of administration; medication therapy monitoring; provision of medication-related information; and counseling to individual patients.

(33) 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.

(A) Authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law. Such authority shall not exceed the scope of practice of the non-physician practitioner. The hospital shall grant appropriate privileges to such non-physician practitioners.

(B) 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 and granted appropriate privileges.

(C) 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) 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
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) 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 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 time frame 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.

(37) Medications shall be administered only by practitioners who have statutory authority to administer or persons who 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 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) Administration by persons who do not have statutory authority to administer shall be included in the quality improvement program.

(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 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
   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) 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. 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.
(39) 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.


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.
Section 1. In addition to other services authorized by law or regulation, a pharmacy technician may perform the functions described in this section if the pharmacy technician is registered as a pharmacy technician pursuant to section 338.013, RSMo and the technician complies with all requirements of subsections 3 to 8 of this section, or any combination thereof, as applicable to the function being performed.

2. Such functions performed pursuant to this section shall only be performed in:
   (1) A setting where the delivery of hospital pharmaceutical services is subject to regulation under sections 197.010 to 197.120, RSMo; or
   (2) A class B pharmacy licensed pursuant to section 338.220, RSMo that is:
       a. Under the common control, management or ownership of a hospital as defined in section 197.020; and
       b. Where medications are administered onsite. To be removed if the proposal is limited to entities under DHSS jurisdiction only.

3. To handle or prepare radiopharmaceuticals, as defined in 20 CSR 2220-2.500, the pharmacy technician shall possess a valid nuclear pharmacy technician certificate issued by an entity that is either accredited by the American Pharmacists Association or its successor organization, or approved by the state board of pharmacy. The provisions of this subsection shall become effective on January 1, 2022.

4. A pharmacy technician or intern pharmacist may verify the final product of prepared by another pharmacy technician in order to ensure an accurate and timely supply of pharmaceuticals when the pharmacist is present if the pharmacy technician or intern pharmacist 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, or by a pharmacy technician certification organization approved by the state board of pharmacy; and
   (2) At least six months of supervised experience in verification of final product, as attested by the Pharmacist-in-Charge.

   (1) For intern pharmacists, a current intern pharmacist license issued by the Board of Pharmacy; and
   (2) For technicians, a valid certificate issued by the Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians or their successor organizations; and
   (3) At least six months of supervised pharmacy technician activity and documented competence in final product verification, as attested by the Director of pharmacy.

5. A pharmacy technician shall not be authorized pursuant to this section to independently verify the accuracy of compounded drugs or the repackaging activities of another technician. The accuracy of such drugs shall be verified by a pharmacist.

6. To act as a pharmacy technician under electronic supervision by a licensed pharmacist at a different site, the pharmacy technician shall have:
   (1) A certification issued by the national Pharmacy Technician Certification Board or its successor organization, or by a pharmacy technician certification organization approved by the state board of pharmacy; and
   (2) One year of experience working as a pharmacy technician, including at least six months experience working as a pharmacy technician in the facility where the verification will be performed or in a facility under common control, management or ownership with the facility where the verification will be performed;

7. No pharmacist shall electronically supervise more than three pharmacy technicians providing pharmaceutical services pursuant to subsection 6 of this section.
8. Nothing in this section shall be construed to modify the authority and responsibility of the Pharmacist-in-Charge to ensure the safe provision of pharmaceutical services.
The Missouri Hospital Advisory Committee met in open session via conference call during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed.

Committee Members Present
Greg Teale, R.Ph., Chairman
Daniel Good, R.Ph., Member
James Gray, R.Ph., Member
Bert McClary, R.Ph., Member
David Wolfrath, R.Ph., Member

Board Members/Staff Present
Christian Tadrus, Bd. of Pharmacy President
Barbara Bilek, Board Member
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector

Others Present
Ron Fitzwater, Missouri Pharmacy Association
Stacey Cassat, Pharmacy Resident
Nathan Hanson, Truman Medical Center
Kathie Thomas, Missouri Dept. of Health and Senior Services (DHSS)
Sarah Willson, Missouri Hospital Association

Chairman Teale opened the meeting at approximately 8:03 a.m. and roll-call was taken.

Agenda Items # 2 & 3 (Review of 19 CSR 30-20.100/Section 338.013): The Committee reviewed suggested revisions to 19 CSR 30-20.100 from the December 6, 2017, meeting. Committee discussion held; Committee recommendations are included in Attachment A. Kimberly Grinston was asked to circulate the changes discussed via e-mail for final review/comments. If no substantive changes are made by a member, Committee consensus to forward suggested changes to the Missouri Hospital Association for final submission to DHSS. Kathie Thomas indicated suggestions need to be received by December 18, 2017, to allow sufficient time for DHSS review and to meet SB 501 timelines.

Agenda Item # 5 (Committee Resignations): Kimberly Grinston reported Kevin Kinkade has retired and officially resigned from the Hospital Advisory Committee as
DHSS’ appointed representative from a smaller hospital. Office staff will ask DHSS to name a replacement.

**AGENDA ITEM # 6 (Future Meeting Dates/Topics)**- Chairman Teale will contact the Board office to identify future meeting dates.

THE HOSPITAL ADVISORY COMMITTEE ADJOURNED BY CONSENSUS AT 9:26 A.M.

________________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
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.
   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 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 electronic supervision of a pharmacist at a remote 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 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.
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<thead>
<tr>
<th>Bill</th>
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<td>HB1261</td>
<td>Schroer, Nick</td>
<td>4881H.01I - Requires a waiver of occupational fees for certain individuals</td>
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<tr>
<td>HB1312</td>
<td>Quade, Crystal</td>
<td>4851H.01I - Changes the laws regarding the dispensing of contraceptives</td>
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<td>[Open Chapter 338; Allows pharmacists to prescribe self-administered oral contraceptives.]</td>
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<tr>
<td>HB1319</td>
<td>Roberts, Steven</td>
<td>4105H.01I - Establishes the Death with Dignity Act to allow patients with terminal illnesses to end their life in a humane and dignified manner [Includes provisions relating to pharmacy dispensing]</td>
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<td>HB1448</td>
<td>May, Karla</td>
<td>4952H.01I - Establishes provisions regarding the legalization of marijuana and establishes certain licensing requirements</td>
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<td>HB1472</td>
<td>Mitten, Gina</td>
<td>4464H.01I - Requires pharmacies to post information regarding the safe disposal of unused pharmaceuticals</td>
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<td>HB1498</td>
<td>Dogan, Shamed</td>
<td>4656H.01I - Modifies provisions relating to dispensing contraceptives</td>
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<td>[Open Chapter 338; Allows pharmacists to prescribe self-administered oral contraceptives.]</td>
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<tr>
<td>HB1524</td>
<td>Neely, Jim</td>
<td>4103H.01I - Allows pharmaceutical companies to communicate off-label treatment uses to health care professionals [Opens Chapter 338]</td>
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<td>HB1540</td>
<td>Morris, Lynn</td>
<td>4982H.01I - Changes the law regarding insurance claims filed at a pharmacy. [Prohibits a health carrier or PBM from paying less than the amount certified]</td>
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<td>HB1542</td>
<td>Morris, Lynn</td>
<td>5330H.01I - Prohibits certain actions by pharmacy benefits managers</td>
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<td>HB1576</td>
<td>Wiemann, John</td>
<td>4190H.03I - Modifies provisions relating to administrative proceedings. [Requires agencies to send copies of any rule that have a fiscal impact of $500 or more to the affected entity. Also requires general assembly approval of any such rule].</td>
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<tr>
<td>HB1587</td>
<td>Helms, Steve</td>
<td>4745H.01I - Creates new provisions of law related to professional registration. [Requires agencies to create a list of disqualifying criminal offenses; Limits criminal offenses]</td>
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that licensing agencies can consider to those identified on the list.]  

<table>
<thead>
<tr>
<th>Bill Number</th>
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| HB1617      | Barnes, Jay     | HB 1617  
 4389H.01I - Modifies provisions relating to telehealth [Applies to MoHealthNet] |
| HB1618      | Barnes, Jay     | HB 1618  
 4387H.01I - Establishes a controlled substance take back program to allow certain health care entities to accept unused drugs for safe disposal [Requires DHSS to establish a take back program] |
| HB1619      | Rehder, Holly   | HB 1619  
 5286H.01I - Establishes the Narcotics Control Act [PDMP Bill] |
| HB1626      | Morris, Lynn    | HB 1626  
 5447H.01I - Establishes the Tricia Leann Tharp Act, which requires certain pharmacists to receive two hours of continuing education on suicide prevention [Suicide CE is not required but would be allowed for pharmacist CE.] |
| HB1710      | Grier, Derek    | HB 1710  
 4386H.01I - Changes the law relating to recognizing licenses to practice occupations or professions issued by other states [Requires licensing Boards to accept non-resident licenses with exemptions if the other state's standards are not comparable or for public protection.] |
| HB1731      | Merideth, Peter | HB 1731  
 5157H.01I - Establishes and modifies provisions relating to the legalization of marijuana |
| HB1740      | Wessels, Fred   | HB 1740  
 5509H.01I - Establishes the Narcotics Control Act [PDMP Bill] |
| HB1752      | Pogue, Jeff     | HB 1752  
 4956H.01I - Prohibits pharmacies in the state from providing emergency contraceptives over the counter |
| HB1790      | Ellington, Brandon | HB 1790  
 5352H.01I - Establishes the Death with Dignity Act to allow patients with terminal illnesses to end their life in a humane and dignified manner |
| HB1810      | Tate, Nate      | HB 1810  
 5147H.01I - Creates the crime of falsifying a drug test |
| HB1870      | Barnes, Jay     | HB 1870  
 5479H.01I - Allows certain medications in multidose containers used by a patient during a hospital stay to be sent with the patient at discharge |
| HB1898      | Swan, Kathryn   | HB 1898  
 5638H.01I - Establishes the Controlled Substance Abuse Prevention Fund |
| HB1837      | Rhoads, Shawn   | HB 1837  
 |
5614H.01I - Changes the laws regarding dispensations of maintenance medications
[Increases the allowed supply to 180 days; Exempts non-resident prescriptions.]

## SENATE BILLS

**SB 718** - Eigel - Modifies a provision relating to maintenance medication filled by pharmacists
[Exempts current supply limits for prescription from non-resident prescribers/military.]

**SB 722** - Sater - Requires the Department of Health and Senior Services to conduct a study regarding the importation of certain prescription drugs by the state

**SB 737** - Schupp - Establishes the Narcotics Control Act [Senate PDMP bill]

**SB 742** - Chappelle-Nadal - Creates a process by which courts may issue a certificate of exemplary conduct and good moral character to certain offenders

**SB 762** - Schatz - Establishes the Narcotics Control Act [Senate PDMP bill]

**SB 776** - Sater - Modifies provisions relating to the administration of vaccines
[Removes the joint promulgation requirement for vaccines by protocol; Limits vaccine by protocol age to CDC/ACIP recommendations. This may present a problem with the shingles vaccine again.]

**SB 825** - Sater - Modifies provisions relating to limitations on prescribing opioids.
[Generally establishes a 7-day supply limit for acute pain unless a medical need is documented.]

**SB 826** - Sater - Modifies provisions relating to the disposal of unused controlled substances. [Allows drug returns for destruction.]

**SB 843** - Riddle - Modifies the composition, duties or repeals outright certain administrative boards, commissions, and councils
Requires certain health care professionals to complete two hours of suicide prevention training as a condition of initial licensure and as a condition of license renewal.
AN ACT

To amend chapter 197, RSMo, by adding thereto one new section relating to multidose medications given to patients at discharge.

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 197.180, to read as follows:

197.180. 1. Medications in multidose containers that were administered to or used for a patient during the patient’s hospital stay may be sent with the patient at discharge if so ordered by an authorized health care provider.

2. Multidose medications shall include, but are not limited to, inhalers, ointments, creams, medications requiring the original container for dispensing, insulin pens and vials, eye drops, ear drops, wearable or on-body medication delivery systems, and infusions that are currently connected to the patient’s infusion device.

3. Multidose medications shall be labeled with the date, patient’s name, prescriber’s name, name and address of the hospital, medication name and strength, instructions for use, and other pertinent information. Labeling shall be performed by a pharmacist, prescriber, or registered nurse. Labeled instructions for use may refer to specific written instructions provided by a pharmacist, prescriber, or registered nurse at the time of discharge.

4. Controlled substances shall not be sent with the patient, except that wearable or on-body medication delivery systems of controlled substances or controlled substance infusions currently connected to the patient’s infusion device may be sent if:

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

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in bold-face type in the above bill is proposed language.
(2) The quantity of the controlled substance sent is documented in the patient's medical record by the person sending the medication; and

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

5. Nothing in this section shall require a class B hospital pharmacy to obtain or comply with additional licensure or regulatory requirements.
license in Missouri or in the non-resident pharmacy’s licensing state/territory. A non-resident pharmacy permit may not be renewed if does not hold a valid pharmacy license in their home state. [§ 338.270]

Note: For non-resident licensure exemptions see 20 CSR 2220-2.025(1).

C.4 APPLICATION REQUIREMENTS

Applicants for a pharmacy permit must file an application with the Board, pay the applicable fee and meet the following requirements:

- The pharmacy must designate and be under the supervision of a “pharmacist-in-charge”;
- Equipment and facilities must be operated in a manner that will not endanger the public health or safety;
- The pharmacy must be equipped with proper pharmaceutical and sanitation appliances;
- The pharmacy must be maintained in a clean, sanitary and orderly manner. Animals are not allowed in the pharmacy, except for service animals as defined by the American with Disabilities Act [20 CSR 2220-2.010(F)]; and
- Proposed/current operations must comply with Chapter 338 and all applicable state/federal law. [20 CSR 2220-2.010(1)(C) – (F), 20 CSR 2220-2.020]

Pharmacies may be owned by unlicensed persons/entities. However, the practice of pharmacy may only be conducted by licensed pharmacists.

✔ In-state pharmacies must pass a Board inspection prior to licensure. Non-resident pharmacies must have an active pharmacy license in the applicant’s home state. The Board may inspect a non-resident pharmacy if deemed necessary.

C.5 CLASS-B HOSPITAL PHARMACY

A Class B Hospital Pharmacy is defined as:

- A pharmacy owned, managed, or operated by a hospital as defined by §197.020, or
- A “hospital clinic or facility” that is under common control, management or ownership of the same hospital or hospital system. [§ 338.165.1(3)].

A Class B pharmacy can provide pharmacy services to the general public, including, to hospital staff and hospital outpatients. A separate Class A Community/Ambulatory pharmacy permit is not required. However, a specialized permit classification would be required for any specialty pharmacy services (e.g., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).

Hospital clinics/facilities eligible for a Class-B permit may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements (this list is not exhaustive). The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board’s jurisdiction. Applicants should consult with legal counsel to determine if a hospital clinic/facility is under “common control, management or ownership of the same hospital or hospital system.” The Board cannot provide legal advice.
Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area and pharmacy activity would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses.

20 CSR 2220-6.055 allows a pharmacist to perform authorized non-dispensing activities at a non-pharmacy location, such as medication therapy management/services, drug utilization review, patient consultation and prescription order entry/review \( (\text{this list is not exhaustive}) \). A Class-B pharmacy permit is not required for allowed non-dispensing activities unless technicians will be assisting at the non-pharmacy location. \( \text{(Note: A pharmacy permit is not required if technicians are only assisting with vaccine administration; See C.16 for additional information).} \)

**Class-B Licensure for Missouri Hospitals**

Under Chapter 197, RSMo, DHSS has regulatory jurisdiction over pharmacy services provided within the “licensed premises” of a Missouri hospital. A Class-B Hospital Pharmacy permit is not required for hospitals “solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by” DHSS. \[\S\ 338.220.6, \text{RSMo}\]. Hospitals solely providing pharmacy services under DHSS’ jurisdiction may choose to be licensed as a Class-B pharmacy although not required.

Section 197.052, RSMo, defines the hospital premises as: “tracts of property which are adjacent but for a common street or highway, as defined in section 300.010, and its accompanying public right-of-way.” Licensees should contact DHSS and their legal counsel to determine what areas are under DHSS’ jurisdiction. The Board cannot provide legal advice.

DHSS has advised that inclusion in the hospital premises is not automatic. Instead, buildings/areas must be officially designated with DHSS as part of the hospital’s license. According to DHSS, this may be done in the hospital’s initial DHSS license application or hospitals may separately notify DHSS to amend their license. Hospitals should contact DHSS to verify that all desired buildings/areas have been properly designated, including any newly added facilities. Pharmacy services provided in buildings/areas that have not been officially included as part of the DHSS licensed hospital premises would be regulated by the Board.

The Board is aware of dually operating Class-B pharmacies providing pharmacy services under DHSS’ jurisdiction and pharmacy services under the Board’s jurisdiction at the same location. Class-B pharmacies may share pharmacy space with a DHSS regulated hospital; the Board does not require physical separation of facilities or drug inventory. However, proper security must be maintained over drug stock at all times. Additionally, pharmacy services under the Board’s jurisdiction must comply with all applicable Board statutes/rules.

**Authorized Class-B Activities**
Section 338.220, RSMo, grants two specific allowances to Class B Hospital pharmacies:

1) Class B Hospital pharmacies may dispense medication by prescription or by “medication order”;

and

2) Class B Hospital pharmacies may distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

Dispensing by Prescription/Medication Order

Section 338.220 authorizes Class-B pharmacies to dispense medication pursuant to a patient-specific prescription or a patient-specific medication order. Prescriptions must comply with all state and federal requirements, including the required two-line format for Missouri prescribers.

A “medication order” is defined as an order for a legend drug or device that is:

1. Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee, and

2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized designee at a hospital or a “hospital clinic or facility” that is under the “common control, management or ownership of the same hospital or hospital system.”

Section 338.165.1, RSMo

Medication orders do not have to be in two-line format, however, orders must comply with all state/federal controlled substance requirements. Missouri law is silent on a pharmacist’s authority to perform generic or biosimilar substitution on a medication order. Please consult an attorney for guidance.

Significantly, medication orders can only be used to dispense medication that will be distributed or administered at a hospital or at a qualifying “hospital clinic or facility.” A qualifying hospital clinic or facility could include offsite physician clinics, urgent-care centers, long-term care facilities, infusion clinics, physical therapy units or other healthcare facilities, provided the clinic or facility is under common control, management or ownership of the same hospital or hospital system.

The Board has been asked if a medication order may be used to dispense a self-contained medication therapy course that will be initially administered onsite but later sent home/transferred with a patient to complete/continue administration (e.g., intrathecal and 5-FU pumps). The Board has determined that a medication order may be used in these instances provided administration is initiated onsite at the hospital or a qualifying hospital clinic or facility but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.

Labeling

Labeling must comply with § 338.059, RSMo (see E. 4 Labeling). The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite
administration to a patient. The Board understands labeling may be a particular issue for hospital-owned clinics/satellite pharmacies that may not use prescriptions or have software to print a traditional “outpatient” prescription label.

The Board intends on addressing this issue by rule in the future. In the interim, Board Inspectors will not cite Class-B pharmacies for violations of § 338.059’s labeling requirements if:

1) Medication is given to a healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy or within the licensed premises of a DHSS licensed hospital, and

2) The medication/prescription container labeling is accurate and complies with DHSS’ medication labeling requirements [see generally 19 CSR 30-20.100(21) which requires patient name, drug name, strength, expiration date, lot number when applicable and other pertinent information. Radiopharmaceuticals must also comply with 19 CSR 30-20.100(18)], and

3) The medication/prescription container is not “given to the patient for use/administration” offsite. The Board will not consider medication to have been given to the patient for offsite use/administration if administration is initiated onsite but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.

Allowed Distribution Without A Missouri Drug Distributor License

Section § 338.165.6 provides a Class B Hospital pharmacy may distribute medication to a “hospital clinic or facility” for patient care or treatment without a Missouri drug distributor license. Once again, a “hospital clinic or facility” is defined as a clinic or facility under common control, management or ownership of the same hospital or hospital system.

Under federal law, a pharmacy may still be required to register with the DEA as a controlled substances distributor if the total dosage units of all controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed during the previous calendar year.

Significantly, a Class B pharmacy may not distribute compounded preparations to other entities.

Licensees can only distribute non-patient specific compounded preparations medication if they are registered with the FDA as a manufacturer or a section 503(b) drug outsourcer under the federal Drug Quality and Security Act. Licensees should consult with legal counsel to ensure compliance with state and federal law.

Record-Keeping

Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. The Board has determined that Class-B pharmacies may maintain dispensing, distribution and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the records must be readily retrievable on inspection or if requested by the Board. Note: Controlled substance records must still be separately maintained/retrievable as required by state/federal law.
20 CSR 2220-2.0XX

(This could either be done as a new rule, placed in the DD section or added to an existing rule).

(1) Definitions.

(A) “Automated Distribution Cabinet” (ADC)- A computerized or electronic drug storage device or cabinet used to store prepackaged medication that electronically tracks and records medication access and drug distribution.

(B) “Electronic Verification System”- An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly placed or loaded into an automated distribution cabinet or drug storage area.

(C) “Health Care Facility”-

1. The practice location of a licensed health care practitioner authorized to prescribe or dispense/administer medication; or

2. An entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility, veterinary facility or a habilitation center as defined by Chapter 630, RSMo.

(D) “Secure Drug Storage Area”- A locked room or other locked area used to store medication that is only accessible to licensed health care practitioners or to designated pharmacy staff as authorized by the pharmacist-in-charge.

(F) “Supervising Pharmacy”- The Missouri licensed pharmacy operating or maintaining an automated distribution cabinet or a secure drug storage area.

(2) A Missouri licensed pharmacy may operate or maintain an automated distribution cabinet (“ADC”) or a secure drug storage area at a health care facility for the purposes of distributing medication to licensed health care practitioners for patient use or administration. An automated distribution cabinet or secure drug storage area may only be used to distribute medication for use or administration by a licensed health care practitioner and shall not be used by, or accessible to, patients or the general public.
(A) A current written or electronic list of all locations/addresses where ADCs or secure drug storage areas are located must be maintained at the supervising pharmacy and available on inspection or request of the Board or the Board’s authorized designee.

(B) A drug distributor license is not required for an automated distribution cabinet or secure drug storage area used solely to distribute medication as authorized by this rule if the total amount of medication annually distributed via an ADC or from a secure drug storage area does not exceed five-percent (5%) of the supervising pharmacy’s total gross sales. For purposes of this rule, total gross sales is calculated based on the pharmacy’s total annual prescription medication sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total annual medication purchases. A drug distributor license is not required for Class B pharmacies exempt from drug distributor license under § 338.165, RSMo.

(C) Pharmacies providing prescription services for residents in long-term care facilities must comply with 20 CSR 2220-2.140, including, pharmacies operate or providing remote dispensing systems in a long-term care facility for emergency dispensing (e.g., an e-kit).

(3) Standards of Operation. The supervising pharmacy and the pharmacist-in-charge shall ensure:

(A) Medication is properly and accurately distributed;

(B) Automated distribution cabinets and secure drug storage areas are operated in compliance with this rule and all applicable state and federal laws, including, any applicable controlled substance laws.

(C) Automated distribution cabinets are maintained in good working order;

(D) Medication is properly stored and maintain within temperature and humidity requirements as provided in the FDA approved drug product labeling or the United States Pharmacopeia (USP). A temperature monitoring system or device must be used to ensure proper temperature storage. Should documentation be required?

(E) No outdated, misbranded or adulterated drugs or devices are stored in an automated distribution cabinet or secure drug storage area;

(F) Medication is labeled in accordance with section 338.059, RSMo, or alternatively labeled with the drug name, strength, expiration date or beyond-use date, lot number and manufacturer/distributor name?

(G) A pharmacist is available to answer questions in person or remotely in the event of an emergency.
(4) Stocking. Automated distribution cabinets and secure drug storage areas may be stocked/re-stocked by a Missouri licensed pharmacist or by a registered Missouri pharmacy technician or intern pharmacist without a pharmacist physically present if-

1. An electronic verification [or other mechanical] system is used to verify medication has been properly stocked or loaded; or

2. The system is stocked using manufacturer unit of use packages or prepackaged containers that have been verified by a pharmacist to ensure the container has been properly packaged and labeled. The identity of the verifying pharmacist must be documented in the pharmacy’s records. Repackaging must comply with 20 CSR 2220-2.130.

(5) Security. Adequate security must be maintained to deter drug theft and diversion.

(A) ADCs and secure drug storage areas shall not be accessible to the public and must be securely placed or located within the designated health care facility. ADCs may not be located in or near exit doors.

(B) All access to an ADC or secured drug storage area must be manually or electronically documented, including, the date and time the ADC/secure area was accessed, the identity of individuals making access and the name, strength, quantity and dosage form of medication placed in, distributed by or removed by each individual.

(C) All medication distributed by an ADC or from a secure area must be reviewed by a pharmacist on a (monthly/weekly) basis to ensure proper distribution. The identity of the pharmacist, date of review and any medication discrepancies or errors must be documented in writing and maintained in the supervising pharmacy’s records.

(D) Medication inventory must be reconciled for each ADC or secure drug storage area every (2-weeks, month/six (6) months). A perpetual inventory must [also] be maintained for any ADC that stocks or provides controlled substances.

(E) Any theft or diversion of or from an automated dispensing system or secure drug storage area must be reported to the Board in writing within fourteen (14) days in a manner designated by the Board. Any suspected or discovered theft or diversion from an automated dispensing system must be promptly investigated and prompt corrective action taken to prevent future theft or losses.
(6) Policies and Procedures. The pharmacy shall establish and follow written policies and procedures to ensure the proper, safe and secure operation of an ADC or secure drug storage area. Policies and procedures must be current and accurate and, at a minimum, include policies and procedures for-

(A) Maintaining the automated dispensing system and any accompanying electronic verification system in good working order;
(B) Ensuring adequate security and accurate stocking and distribution of the system;
(C) Reporting, investigating, and addressing known or suspected errors, system malfunctions, thefts/diversion or security breaches;
(E) Tracking, documenting and investigating medication errors;
(F) Conducting routine and preventive maintenance and, if applicable, calibration;
(G) Removing expired, adulterated, misbranded, or recalled drugs;
(H) Monitoring and preventing unauthorized access to the system, including, assigning, discontinuing, restricting or changing security access as deemed necessary or appropriate; and
(I) Ensuring compliance with state and federal law, including, all applicable controlled substance laws.

(7) Records. Distribution records must be maintained for all medication stocked in, distributed by or removed from an ADC or a secure drug storage area. At a minimum, distribution records must include the date of distribution and the identity, quantity and dosage form of medication distributed or removed. Except as otherwise provided by law or other rule of the Board, all records required by this rule shall be manually or electronically maintained in the supervising pharmacy’s records for a minimum of two (2) years and available on inspection or request of the Board.

(8) This rule is solely applicable to pharmacies operating an ADC or secure drug storage area pursuant to this rule. This rule does not apply to compounding, administering, prescribing or dispensing of medication by a non-pharmacist healthcare practitioner as otherwise authorized by law.