

**Meeting Notice
Missouri Board of Pharmacy
Hospital Advisory Committee**

**August 26, 2016, 10:00 a.m.
Missouri Hospital Association
4712 Country Club Drive
Jefferson City, MO 65109**

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy's Hospital Advisory Group is authorized to close meetings, records and votes pursuant to Section 610.021(1).

The Group may go into closed session at any time during the meeting pursuant to § 610.021(1) for purposes of legal advice. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Hospital Association, 4712 Country Club Drive, Jefferson City, Missouri, at 10:00 a.m. on June 3, 2016. 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
Meeting Notice
Missouri Board of Pharmacy
Hospital Advisory Committee

August 26, 2016, 10:00 a.m.
Missouri Hospital Association
4712 Country Club Drive
Jefferson City, MO 65109

1. Approval of Minutes
2. Review of Administration by Medical Prescription Order Rule (20 CSR 2220-6.040)
3. Board Updates
4. DHSS Updates
5. Potential Class-B Pharmacy Rule Suggestions
6. Board of Pharmacy/DHSS Jurisdictional Conflicts/Questions
7. Use of Automated Devices in Class-B Settings
8. Access to Class-B Pharmacies by Other Healthcare Practitioners
9. Pharmacist Scope of Practice in Class-B v. Hospital Settings
 - a. MTS in dually regulated practice settings (Bd/DHSS)
 - b. Prescribing authority
 - c. Controlled substance authority
 - d. Advance practice pharmacist designation
10. Technician Scope of Practice in Class-B Pharmacies/Dually Regulated Settings
11. Regulation of other health care entities
12. BOP/DHSS Funded Pharmacist
13. Future Meeting Dates/Topics

**Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care
Standards**

20 CSR 2220-6.040 Administration by Medical Prescription Order

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

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices, including vaccines, pursuant to a medical prescription order.

(2) Definitions. The following definitions shall apply for purposes of this rule:

(A) “Health Clinic or Facility”- A clinic or facility under the common control, management, or ownership of the same hospital or hospital system.

(B) “Hospital”- A hospital as defined in section 197.020.

(C) “Medical Prescription Order”- A lawful order for drugs or devices issued by an authorized practitioner within the scope of his/her professional practice which is to be dispensed or administered to the ultimate user or recipient.

~~(2)~~(3) The pharmacist may not delegate the administration to another person, except to an ~~pharmacist intern~~ intern pharmacist who has met the qualifications under subsections ~~(3)(B), (C), and (E)~~ (4)(B) - (D) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order. The pharmacist and pharmacist intern shall maintain proof of the intern’s compliance with this subsection.

~~(3)~~(4) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the state Board of Pharmacy. To file a Notification of Intent, a pharmacist must—

(A) Hold a current, ~~unrestricted~~ license to practice pharmacy in this state;

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(B) Hold a current ~~provider level cardiopulmonary resuscitation (CPR) Basic Life Support~~ certification (BLS) issued by the American Heart Association, ~~or~~ the American Red Cross or an equivalent organization. The certificate program must include a live training component;

(C) Successfully complete a certificate program in the administration of drugs accredited provided by: ~~the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy~~ (1) a continuing education provider accredited by the Accreditation Council for Pharmacy Education (ACPE) or (2) a governmental entity, healthcare professional organization or educational institution approved by the Board. To obtain Board approval, the training program must be taught by qualified instructors/a licensed healthcare professional and provide instruction in: ~~The certificate program must cover a~~

1. Physiology and techniques for routes of administration which must include hands-on training in all routes of administration the pharmacist utilizes;
2. Drug storage and handling;
3. Informed consent requirements, if applicable;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal; and
6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks; and

(D) ~~Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;~~

~~(E) Maintain documentation of the above requirements; and~~

~~(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section. (E) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist shall first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized~~

Comment [GK1]: The Committee did not make a final recommendation on the highlighted language.

to administer medication. Documentation of the required training shall be maintained at the pharmacy and available to the Board upon request.

(4) (5) General Requirements.

(A) A pharmacist shall administer ~~drugs~~ vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC) ~~or in accordance with manufacturer's guidelines. In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.~~

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs by medical prescription order, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. ~~The manual Policies and procedures~~ shall be reviewed annually by the pharmacist-in-charge. Policies and procedures must be available for inspection by the State Board of Pharmacy or other authorized Board representative. Documentation of the annual review must be maintained in the pharmacy's records. At a minimum, the required policies and procedures must include provisions governing:

1. Drug administration procedures, including, authorized routes of administration,
2. Drug storage;
3. Pre- and post- administration assessment and counseling, including, providing vaccine information statements when applicable;
4. Biohazard waste disposal and disposal of used/contaminated supplies;
5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.

(D) Drugs must be stored within the manufacturer's labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.

(E) Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

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~~(F) For pharmacists administering drugs in a, the policy and procedure review required by this subsection may be performed by the pharmacist in charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the responsible for reviewing clinical practices.~~

~~(5)~~ (6) Requirements of Medical Prescription Order. The medical prescription order from a ~~licensed prescriber~~ an authorized practitioner must contain at a minimum the following:

- (A) The name of the ~~licensed prescriber~~ authorized practitioner issuing the order;
- (B) The name of the patient to receive the drug;
- (C) The name of the drug and dose to be administered;
- (D) The route of administration;
- (E) The date of the original order; and
- (F) The date or schedule, if any, of each subsequent administration; ~~and~~
- ~~(G) A statement that the drug is to be administered by a pharmacist.~~

~~(6)~~ (7) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy. For drugs administered by a pharmacist for or on behalf of a hospital or a hospital clinic or facility, the information required herein may be recorded in a patient medical record that the hospital clinic or facility is required to maintain under state or federal law.

- 1. The name, address, and date of birth of the patient;
- 2. The date, route, and anatomic site of the administration;
- 3. The name, dose, manufacturer, ~~lot number,~~ and expiration date of the drug. The lot number shall be documented and recorded for vaccines and biologics;
- 4. For vaccines, ~~the~~ the name and address of the patient's primary health care provider, as identified by the patient. The pharmacist shall document in the patient's immunization record if a patient's primary health care provider is unknown or not designated by the patient;
- 5. The ~~name or identifiable initials~~ identity of the administering pharmacist. If administered by an intern pharmacist, the identity of the intern and the supervising pharmacist; and
- 6. The nature of an adverse reaction and who was notified, if applicable;

Comment [GK2]: Should this be that a "hospital" is required to maintain under state or federal law?

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7. A patient's refusal or failure to remain in or return to the pharmacy as requested after vaccine administration to observe any adverse reactions; and

8. Written or electronic documentation that required notifications have been sent.

(B) All records required by this ~~regulation~~ rule shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. Records may be securely stored offsite at a location designated by the pharmacy, provided records must be produced as provided in section (11) of this rule.

(C) Production of Records. Records required by this rule shall be maintained either electronically or physically for two (2) years and shall be readily retrievable and subject to inspection by the board of pharmacy or its agents. At a minimum, records maintained at the pharmacy shall be physically or electronically produced immediately or within two (2) hours of a request from the Board or the Board's authorized designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Board and/or its authorized designee.

~~(7)~~ (8) Notification Requirements.

(A) A pharmacist administering ~~drugs~~ a vaccine pursuant to a medical prescription order shall notify the ~~prescriber within seventy-two (72) hours~~ patient's primary health care provider, if provided by the patient, within fourteen (14) days after administration of the following:

1. The identity of the patient;
2. The identity of the ~~drug~~ vaccine administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) In the event of any adverse event or reaction experienced by the patient following administration of a drug, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. The prescriber may not opt out of adverse event notification requirements.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

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(D) Documentation that the required notifications have been sent must be kept at the pharmacy or other authorized location where the prescription order is maintained.

(9) Notification of Intent Refiling. A Notification of Intent to administer drugs by medical prescription order shall be refiled with the state board of pharmacy biennially along with the pharmacist's Missouri pharmacist license. To refile, a pharmacist must:

(A) Hold a current Basic Life Support certification issued by the American Heart Association or the American Red Cross or an equivalent organization. The certification program must include a live training component; and

(B) Have successfully completed four (4) hours of continuing education (0.4 CEU) related to drugs administration. The required continuing education (CE) shall be governed by the rules of the state Board of Pharmacy governing pharmacist CE and may be used to satisfy the pharmacist's biennial pharmacist renewal CE requirements. The initial training program required by subsection (4) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within twelve (12) months prior to refiling the pharmacist's Notification of Intent.

(10) Administration in a Hospital Clinic or Facility- Pharmacists administering medication under the jurisdiction of the Board on behalf of a hospital or a health care clinic or facility shall comply with the requirements of this rule with the following exceptions:

(A) A pharmacist shall be deemed in compliance with the requirements of sections ~~(5)~~, ~~(6)~~, (7) and (8) of this rule if the pharmacist administers drugs for or on behalf of a hospital or a hospital clinic or facility in compliance with this section and the administration is lawfully recorded in a patient medical record that is required to be maintained by the hospital or the hospital clinic or facility pursuant to state or federal law.

(B) In lieu of completing a certificate program in the administration of drugs as required by section (4) of this rule, pharmacists administering in a hospital or a hospital clinic or facility shall be trained in administration and meet all competency, training and evaluation requirements required by the hospital or hospital clinic or facility and the Missouri Department of Health and Senior Services (DHSS). At a minimum, pharmacist administration training must be similar to or include the training components identified in section (4)(C).

Comment [GK3]: Did the Committee intend on exempting these pharmacists from sections (5) and (6)?

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(C) A pharmacist shall administer vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC). In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

(E) The policy and procedure review required by section (5) may be performed by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the hospital responsible for reviewing clinical practices. Required policies and procedures may be maintained in or included with the governing hospital's approved policies, procedures or protocols.

(F) This section is only applicable to pharmacy services under the jurisdiction of the Board and is not applicable to hospital pharmacy services or pharmacist medication administration under the jurisdiction of the Department of Health and Senior Services.

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Comment [GK4]: Our notes indicate the Committee extensively discussed if the P&P review should be required but we did not record a final consensus. Please clarify the Committee's preference

AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and section 338.010.1, RSMo Supp. 2007. Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

HAC Future Topics

5.12.16

Bert

BOP jurisdiction

- Statutory requirements
- License requirements
- DHSS licensed premises vs non-licensed areas
- Specific BOP rules applicable to DHSS licensed premises
- Enforcement of DHSS rules
- Enforcement of other jurisdiction rules—federal, state
- Professional standards of practice—USP, TJC, ISMP, ASHP

Joint rules w/ DHSS

- Determine which DHSS pharmacy rule sections are joint
- Specific topics
- Publish as BOP rules
- Include in the proposed BOP hospital rule

Practice Guide

- Separate guide, and tab with summary in current guide
- Topics from previous HAC discussions-see HAC minutes
- Topics from webinar questions
- Topics from questions from individuals answered by BOP and DHSS

BOP “hospital rule” for hospitals/health systems

- Different rules for hosp/health system vs non-hosp HCE
- Review def HCE
- Need specific allowances re Class B
 - Infusion pharmacies
 - Other clinic services
- Evaluate current rules that apply (& statutes)
- Determine which are unsuita
- How should they be changed
- Which need to be joint rules w/ DHSS
- Evaluate current DHSS rules for which s/b joint rules w/ BOP
- See Consistency in Practice document in Hosp BOP Rule folder

Pharmacist scope of practice

- MTS
- Prescribing authority
 - AJHP prescribing theme issue to be in Sept 2016 issue
- CS authority
- Advanced practice pharmacist designation

MTS

- Revise 080 MTS protocols to exempt HCE from notific & records as proposed for 040
- Types of protocols based on relationship w/ physician(s)
- Protocols w/ medical committee
- Guidance for protocol format, content
- Guidance for credentialing & privileging

APRN/PA relationship w/ MTS orders

Technician scope of practice

- Education, training, competency requirements
- Certification, licensure
- Pharmacist check non-patient labeled distribution
- Expand scope of practice through joint BOP/DHSS rules

Other practice locations/health care entities

- BOP oversight/authority, other agency rules
- Review definition of health care entity

Automation

- Robots, compounders, automated dispensing cabinets, barcodes
- Clinical systems
- Accuracy checks
- Tech scope of practice: automation-check-tech, remote supervision

BOP/DHSS Hospital Pharmacist

- Both BOP and DHSS should fund a full-time hospital pharmacist position
- Evaluate joint funding/joint position options
- DHSS contract for BOP services

Expanding Board Membership

- Gather data re number of practitioners in specialty areas of practice.
- Consider impact of specialty areas on overall patient care.
- Consider knowledge/procedures that are different for specialty areas.

Pharmacist staffing

- Level/quality in small rural hospitals, CAHs
- CMS/DHSS requirements/qualifications
- Minimum hours onsite
- 24/7 onsite/on-call
- Hours/bed ratio

LTCF distribution issues

- BOP current statutes/rules for LTCF
- Does LTCF rule apply if pharmacy only distributing to LTCF, not filling OP Rx's
- This probably applies rarely, most will fill Rx's also, but maybe not if no BOP license
- Current distribution to facility for e kits is OK, so distrib should not be problem

Review definitions for terms prescribe, prescriber, prescription, order, medical prescription order, authorized practitioner, standing order, protocol, MTS protocol, etc

(my proposed definitions in Prescribing & MTS folders, prescribing documents)

Review hospital practice questions received by BOP, DHSS, MHA, MSHP