

OPEN MINUTES
Missouri Board of Pharmacy
Hospital Advisory Committee Meeting Conference Call

March 2, 2016

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

Bert McClary, R.Ph., Chairman
James Gray, R.Ph., Member
Colby Grove, R.Ph., Member
Kevin Kinkade, R.Ph., Member
Neil Schmidt, R.Ph., Member
Greg Teale, R.Ph., Member

Committee Members Absent

Daniel Good, R.Ph.

Staff Present

Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector

Others Present

Christian Tadrus, R.Ph., Board Member
Sarah Wilson, Missouri Hospital Association
Julie Creach, Missouri DHSS

Chairman McClary opened the meeting at 12:01 p.m. and roll-call was taken of meeting attendees. Mr. McClary indicated the administration by prescription order rule and the DHSS hospital related pharmacy rules/proposed rules would be the main agenda items. Greg Teale indicated he's established a google survey to allow members to submit questions for the SB 808 webinar and asked if the link should be sent to other groups. Neil Schmidt indicated he intended to circulate the SB 808 list to MSHP members after the questions have been selected.

Agenda Item # 1: Mr. McClary asked for updates on the proposed DHSS rule. Kimberly Grinston reported the Board previously reviewed the suggestions and did not make any additional changes.

Agenda Item # 2: Bert McClary asked for additional changes/suggestions to the administration by prescription order rule. Committee discussion was held. Substantive

rule changes/suggestions are incorporated in Attachment A. Additionally, the following discussion was held:

- Greg Teale asked if the required administration training programs actually exist and asked if this should be handled in the same manner as competency assessment. Alternatively, Mr. Teale asked if this issue was already addressed in proposed section (10). Bert McClary indicated the rule is applicable to all pharmacists which may require the duplicate language but noted that the current rule or proposed changes do not address a licensed pharmacy within a health care entity. Sarah Wilson also questioned the availability of training programs and asked if additional training was necessary outside of what may have been learned in pharmacy school. Ms. Wilson also noted that hospitals may provide orientation programs but may not provide full training programs in administration technique and practices. Bert McClary indicated older pharmacy school graduates may not have received training in drug administration and questioned if this was covered in current pharmacy school curriculums. Neil Schmidt indicated recent PharmD. graduates may have received administration training. Mr. McClary suggested hospital training should be acceptable.

Sarah Wilson suggested that the rule focus should be on safe administration practices and commented that all pharmacists should be held to the same level of administration training and competency assessment. Kimberly Grinston asked if the rule should address training or competency assessment and indicated these are different activities. Committee members inquired about training requirements for other unlicensed medical assistants such as nursing assistants or LPNs or certified medication technicians. Sarah Wilson indicated that the Board of Healing Arts may allow physicians in private office practices to designate administration activities to unlicensed staff if properly trained. Bert McClary again commented that the original rule intent was to set a practice standard for all pharmacists administering medication.

Mr. Teale cautioned against establishing standards for a Class B hospital and different standards for hospital functions under the jurisdiction of DHSS. Sarah Wilson agreed and indicated this would be a problem for numerous hospitals. James Gray agreed and asked if the proposed rule could require a single standard for hospitals and related hospital administrations. Bert McClary suggested that Committee members bring suggestions for addressing the training and Class B issues to a future meeting.

- Bert McClary questioned if hospitals would have a specific policy just for pharmacist administration and asked if hospitals should be exempt from the policy and procedure section. Greg Teale suggested hospitals would likely have administration criteria that would be applicable to pharmacists based on their role. Julie Creach indicated she would check DHSS rule requirements. Greg Teale suggested striking the policy & procedure requirements for hospitals pending DHSS' answer. However, Neil Schmidt commented some hospital policies may not include pharmacy and suggested it might be beneficial for hospitals to develop policies that are pharmacy/pharmacist specific.

Agenda Item # 3: Bert McClary introduced the topic and indicated his intent was to make the Committee aware of other DHSS rules that may affect hospital pharmacy practice. Kimberly Grinston asked if technicians would fall under the UAP rule. Bert McClary indicated he could not provide a definitive answer but suggested that technicians could likely fall under both the UAP and pharmacy technician definitions depending on their duties. Due to time constraints on the call, Bert McClary suggested revisiting the DHSS rules at a future meeting.

Agenda Item # 7 & # 8: Neil Schmidt suggested that the Committee meet every other month in-person and via conference call during the interim month. Committee consensus to meet as suggested for now. Bert McClary requested that the Committee discuss future meeting formats at a later meeting. The Committee agreed to meet in Jefferson City on April 11, 2016.

ADJOURNMENT

Bert McClary adjourned the meeting by consensus at approximately 2:04 p.m.



KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved: 05/06/2016

**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:

(1) “Health Care Entity”- A health care entity shall include any entity or organization, other than a pharmacy licensed under Chapter 338, RSMo, that is licensed or certified by the state or federal government to provide health care services and that is required to maintain patient medical records by state or federal law.

(2) “Medical Prescription Order”- A lawful order for 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;

(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 health care practitioner who is proficient in that~~

route of administration. The pharmacist shall provide the Board with a written statement from the health care practitioner attesting that both the health care practitioner and the pharmacist are proficient in that route of administration.

(4) (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 or, for a licensed pharmacy in a health care entity, policies and procedures may be alternatively reviewed by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the health care entity responsible for reviewing clinical practices. 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.

(F) For pharmacists administering drugs in a health care entity, 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 health care entity 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 health care entity, the information required herein may be recorded in a patient medical record that the health care entity 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 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;

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

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

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

~~(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 notification requirements.

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

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

(9) Notification of Intent Refiling. A Notification of Intent to administer drugs by medical prescription order shall be refilled with the state board of pharmacy biennially along with the pharmacist's Missouri pharmacist license. To refile, 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 Health Care Entity- Pharmacists administering drugs in a health care entity 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 health care entity and the administration is lawfully recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law.

(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 health care entity shall be trained in administration and meet all competency, training and evaluation requirements required by the health care entity and the Missouri Department of Health and Senior Services (DHSS).

(C) If a pharmacist administering drugs in a health care entity 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 health care practitioner who is proficient in that route of administration. The pharmacist shall provide the

Board with a written statement from the health care practitioner attesting that both the health care practitioner and the pharmacist are proficient in that route of administration.

(D) A pharmacist shall administer vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC).

(E) The policy and procedure review required by section (5) shall be performed by the pharmacist-in-charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the health care entity responsible for reviewing clinical practices.

(F) The records required by this rule may be securely stored offsite at a location designated by the health-care entity, provided records must be produced as provided in section (11) of this rule.

(11) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation as requested by the Board or the Board's authorized designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Board and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

*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.*