

Meeting Notice

Missouri Board of Pharmacy and Missouri State Board of Registration for the Healing Arts Joint Rulemaking Subcommittee

**Conference Call
September 16, 2009 8:30 a.m.
Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109**

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.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13) and (14) and under Section 324.001.8.

The Joint 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.

If any member of the public wishes to attend the open portion of the telephone conference call, s/he should be present at the Division of Professional Registration, Main Conference Room, 3605 Missouri Blvd, Jefferson City, Missouri, at 8:30 a.m. on September 16, 2009. Board of Pharmacy participants will be joining the conference call from the Courtyard by Marriott, Columbia, Missouri.

Please see attached tentative agenda for this meeting.

**TENTATIVE AGENDA
September 16, 2009 8:30 a.m.**

**Missouri Board of Pharmacy
and
Missouri State Board of Registration for the Healing Arts
Joint Rulemaking Subcommittee**

**Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109
Conference Call**

OPEN SESSION

- 1 Call to Order
- 2 Roll Call
- 3 20 CSR 2220-6.050 Administration of Influenza Vaccines By Protocol
20 CSR 2220-6.055 Authorized Non-Dispensing Activities
- 4 The Joint Committee may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (3), (5), (7), (13) and (14) and under Section 324.001.8. The Board will return to open session at the conclusion of discussion of closed session items.
- 5 Adjournment

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

20 CSR 2220-6.050 Administration of ~~Influenza~~ Vaccines Per Protocol

*PURPOSE: This rule establishes the procedures for pharmacists to administer ~~viral influenza vaccinations~~ **vaccines** per written protocol with a physician.*

~~(1) A pharmacist may administer viral influenza vaccinations:~~

~~(A) To persons twelve (12) years of age or older; and~~

~~(B) Pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine in the state of Missouri.~~

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.

(A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance within manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under 12 years of age.

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

(2) A pharmacist may not delegate the administration of ~~viral influenza vaccinations~~ **vaccines** to another person, except to a pharmacist intern who has met **the** qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer ~~viral influenza vaccinations~~ **vaccines**.

(3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, ~~the viral influenza vaccinations~~ **vaccines** administered by the pharmacist.

(4) Pharmacist Qualifications—A pharmacist who is administering ~~viral influenza vaccinations~~ **a vaccine authorized by Chapter 338, RSMo**, must:

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

(B) Hold a current ~~provider level~~ cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross ~~or equivalent~~;

(C) Successfully complete a certificate program in the administration of ~~viral influenza vaccinations~~ **vaccines** accredited by the Accreditation Council for Pharmacy Education (ACPE) ~~or a similar health authority or professional body approved by the State Board of Pharmacy~~;

(D) Maintain documentation of the above certifications;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education **as defined by 20 CSR 2220-2.100**, per **calendar** year related to **vaccine** administration ~~of viral influenza vaccinations~~. 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;

(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering ~~viral influenza vaccinations~~ **vaccines**; and

(G) On a yearly basis prior to administering ~~viral influenza vaccinations~~ **vaccines**, establish a new protocol with the authorizing physician and 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), (E), and (F) of this section.

~~(5) General Requirements.~~

~~(A) A pharmacist shall administer viral influenza vaccinations in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.~~

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

~~(65) Administration by Written Protocol with a Missouri Licensed Physician.~~

(A) A pharmacist may enter into a written protocol with a physician for the administration of ~~viral influenza vaccinations~~ **any vaccine authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines** to patients **under twelve (12) years of age or older.** The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the ~~viral influenza vaccinations~~ **vaccine**. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the ~~viral influenza vaccination~~ **vaccine(s)** which may be administered;
4. The identity of the patient or groups of patients to receive the authorized ~~viral influenza vaccination~~ **vaccine(s)**;
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street address(es) of the pharmacy **or other locations** at which the pharmacist may administer the authorized ~~viral influenza vaccination~~ **vaccine(s)**;
11. Record keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol, **and any subsequent amendments or alterations**, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the

beginning of implementation to a minimum of eight (8) years after termination of the protocol.

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

(A) A pharmacist ~~who administers a viral influenza vaccination~~ **administering vaccines pursuant to this rule** shall maintain ~~a the following~~ records ~~regarding of~~ each administration **which shall include:** ~~—These records must be separate from the prescription files of a pharmacy and include:~~

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 ~~vaccination~~ **vaccine;**
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by section (6)(A) of this rule are promptly delivered to the pharmacy,

~~(B) All administrations of viral influenza vaccinations must have a prescription as authorized by protocol on file within seventy two (72) hours after administration at a pharmacy documenting the dispensing of the drug.~~

~~(C) All records required by this regulation shall be kept by the pharmacist and be available for two (2) years from the date of such record, for inspecting and copying by the authorizing physician, the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives.~~

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the Board.

(D) The records required by this rule shall be maintained securely and confidentially as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the prescription files of the pharmacy. If the vaccine is not being administered on behalf of a pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine.

2. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the Board and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

~~(8)~~ **(7) Notification Requirement.**

(A) A pharmacist administering ~~viral-influenza-vaccinations~~ **vaccines authorized by Chapter 338, RSMo**, shall notify the authorizing physician within seventy-two (72) hours after administration of the following:

1. The identity of the patient;
2. The identity of the ~~viral-influenza-vaccination~~ **vaccine(s)** administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) The pharmacist shall provide a written report to the patient's primary health care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.

(C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient's primary health care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

(D) A pharmacist administering ~~viral-influenza-vaccinations~~ **vaccine(s)** shall report the administration to all entities as required by state or federal law.

(E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule.

AUTHORITY: section 338.010, RSMo Supp. 2007 and section 338.140, RSMo 2000.
Emergency rule filed Oct. 24, 2007, effective Nov. 3, 2007, expired April 30, 2008. Original rule filed Oct. 24, 2007, effective May 30, 2008.*

Original authority: □338.010, RSMo 1939, amended 1951, 1989, 1990, 2007 and 338.140, RSMo 1939, amended 1981, 1989, 1997.

NEW PROPOSED RULE

20 CSR 2220-6.055- Authorized Non-Dispensing Activities:

(1) Pursuant to § 338.220, RSMo, a pharmacist may perform the following non-dispensing activities outside of a licensed pharmacy:

- a. Patient counseling/education, as authorized by Missouri law, provided the pharmacist shall be obligated to comply with 20 CSR 2220-2.190, when applicable;
- b. Obtain patient history/information;
- c. Review patient records/medical histories;
- d. Patient assessment/evaluation, as authorized by Missouri law;
- e. Billing and insurance claim submissions/review;
- f. Drug utilization review;
- g. Assess health plan and medication eligibility/coverage;
- h. Pharmacy compliance audits/evaluations;
- i. Administer drugs , vaccines or biologicals, as authorized by law and the rules of the Board;
- j. Peer review/peer consultations;
- j. Review, select and develop formularies or plan/practice guidelines;
- k. Review compliance with benefit guidelines;
- l. Manage inventory, including, purchasing and ordering;

- m. Manage/review information systems;
- n. Patient medication review;
- o. Consultation with other health care professionals;
- p. Patient referrals;
- q. Prescription order entry/review, provided that a pharmacist shall only be authorized to accept a prescription on the premises of a Missouri licensed pharmacy, as required by § 383.095.5, RSMo.;
- r. Medication therapy management, pursuant to and as authorized by Chapter 338 and the rules of the Board.

(2) Confidentiality. A pharmacist performing non-dispensing activities pursuant to this rule shall comply with all applicable state and federal confidentiality laws and regulations and shall provide sufficient storage and security for confidential documents and electronic data processing hardware. In addition, data processing systems must utilize sufficient security software to ensure confidentiality and prevent unauthorized access. Any breach in the security or confidentiality of the data processing systems or confidential documents shall be documented and reported to the board in writing within seven (7) days of the breach.

(3) Notwithstanding any other provision of this rule, a pharmacist shall not meet with patients in the pharmacist's residence or living quarters.

(4) A pharmacist performing non-dispensing activities pursuant to this rule shall ensure compliance with Chapter 338 and the rules of the Board at all times. Nothing in this rule shall be construed to eliminate or otherwise exempt any pharmacist from the record-keeping, confidentiality or security requirements otherwise imposed by Chapter 338 or the rules of the Board. Violations of this section shall constitute grounds for discipline.

(5) This rule shall not be construed to authorize a pharmacist to conduct the unauthorized practice medicine or to conduct any activity for which a license is required pursuant to Chapters 330, 331, 332, 334 or 337, RSMo.

(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the Board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.