Rules of
Department of Insurance, Financial Institutions and Professional Registration
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION

Division 2220—State Board of Pharmacy

Chapter 6—Pharmaceutical Care Standards

20 CSR 2220-6.030 Provision of Drug and/or Medical Information

PURPOSE: The purpose of this rule is to define requirements for the provision of drug and/or medical information by pharmacists.

(1) Section 338.095.3., RSMo provides in part that a pharmacist may lawfully provide prescription or medical information to a licensed health care provider or his/her agent who is legally qualified to administer medications and treatments and who is involved in the treatment of the patient. The information may be derived through direct contact with a prescriber or through a written, agreed upon protocol or standing prescription order from an authorized prescriber.

(2) Information transfers as described in section (1) may take place within any practice setting as long as the pharmacist maintains an active license with the Board of Pharmacy.

(3) Information transfers between two (2) licensed pharmacists may occur as long as the pharmacist receiving that information documents in a uniform and readily retrievable fashion, the identity of the pharmacist providing the information transfer, the origin of his/her authority to provide the drug or medical information, the date and the identity of the receiving pharmacist.

(4) When a transfer of prescription information for the purpose of filling an original prescription occurs, all provisions of 4 CSR 220-2.120 must be followed, except for subsection (1)(C) and paragraphs (2)(B)4.–6.

(5) Any laws governing prescription records, dispensing procedures and controlled substances must be adhered to when a transfer of prescription information for the purpose of filling an original prescription occurs.

AUTHORITY: sections 338.095, RSMo Supp. 1993, 338.010, RSMo Supp. 1990, 338.140, RSMo Supp. 1989 and 338.280, RSMo 1986. This rule originally filed as 4 CSR 220-6.030. Original rule filed March 1, 1994, effective Sept. 30, 1994. Moved to 20 CSR 2220-6.030, effective Aug. 28, 2006.*

**Original authority: 338.280, RSMo 1951, amended 1971, 1981; 338.010, RSMo 1939, amended 1951, 1989, 1990; and 334.104.4. and 338.095, RSMo 1993.*

20 CSR 2220-6.040 Administration by Medical Prescription Order

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

(1) A pharmacist may administer drugs pursuant to a medical prescription order.

(2) The pharmacist may not delegate the administration to another person, except to a pharmacist intern who has met qualifications under subsections (3)(B), (C), and (E) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order.

(3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order 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 drugs accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy. The certificate program must cover all routes of administration the pharmacist utilizes;

(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.

(4) General Requirements.

(A) A pharmacist shall administer drugs 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.

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. The manual shall be reviewed annually and be available for inspection by the State Board of Pharmacy or authorized representative.

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

(A) The name of the licensed prescriber 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;

(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) 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.

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;

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) 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 State Board of Pharmacy and/or its authorized representatives.

(7) Notification Requirements.

(A) A pharmacist administering drugs pursuant to a medical prescription order shall

notify the prescriber within seventy-two (72) hours after administration of the following:

1. The identity of the patient;
2. The identity of the drug 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, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction.

(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.

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.*

20 CSR 2220-6.050 Administration of Influenza Vaccines Per Protocol

PURPOSE: This rule establishes the procedures for pharmacists to administer viral influenza vaccinations 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.

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

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

(4) Pharmacist Qualifications—A pharmacist who is administering viral influenza vaccinations 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 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 per year related to 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; and

(G) On a yearly basis prior to administering viral influenza vaccinations, 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.

(6) 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 to patients 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. 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 which may be administered;
4. The identity of the patient or groups of patients to receive the authorized viral influenza vaccination;
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 of the pharmacy at which the pharmacist may administer the authorized viral influenza vaccination;
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 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) Record Keeping.

(A) A pharmacist who administers a viral influenza vaccination shall maintain the following records regarding each administration. 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;

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) 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.

(8) Notification Requirement.

(A) A pharmacist administering viral influenza vaccinations 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 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 shall report the administration to all entities as required by state or federal law.

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.