Mo. Code Regs. tit. 20 § 2220-6.040

Section 20 CSR 2220-6.040 - Administration by Medical Prescription Order

PURPOSE: This amendment updates and clarifies requirements for pharmacists administering medication by prescription order.

PURPOSE: This rule establishes procedures for pharmacists to administer medication pursuant to a medical prescription order.

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices pursuant to a medical prescription order, including vaccines.
(2) Except as otherwise provided by law, a pharmacist may not delegate medication administration to another person, except to an intern pharmacist who has met the qualifications under subsections (3)(B)-(E) and is working under the direct supervision of a pharmacist who has met the qualifications to administer drugs pursuant to a medical prescription order. Proof of an intern's compliance with subsections (3)(B)-(E) must be maintained by both the supervising pharmacist and the intern pharmacist for a minimum of two (2) years.
(3) 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 board. To file a Notification of Intent, a pharmacist must-

(A) Hold a current Missouri pharmacist license;

(B) Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) certification or Basic Life Support certification issued by the American Heart Association , the American Red Cross, or an equivalent organization. The certificate program must have included an in-person skills assessment;

(C) Have successfully completed a certificate program in medication administration and emergency procedures accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or approved by Board of Pharmacy. The required training program must provide instruction in-

1. Administration techniques, including hands-on training in routes of administration;

2. Drug storage and handling;

3. Informed consent requirements;

4. Pre- and post- administration assessment and counseling;

5. Biohazard waste disposal; and

6. Identifying and treating adverse reactions, including ana-phylactic reactions and needle sticks;

(D) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist must first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of the required training and training date(s) must be maintained at the pharmacy and available to the board on request; and

(E) Proof of compliance with this section must be maintained for a minimum of two (2) years.

(4) General Requirements.

(A) Medication must be administered in compliance with all applicable state and federal laws, including applicable Vaccine Information Statements and informed consent requirements. Except as otherwise authorized by law, vaccines must also be administered in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.

(B) Pharmacists must have a current and accurate written policy and procedure manual covering all aspects of administering drugs by medical prescription order, including:

1. Drug administration procedures;

2. Authorized routes of administration;

3. Drug storage;

4. Pre- and post- administration assessment and counseling;

5. Biohazard waste disposal and disposal of used/contaminated supplies;

6. Identifying and handling acute adverse events or immunization reactions, including anaphylactic reactions; and

7. Recordkeeping and notification procedures and requirements.

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

(D) Patients must be asked to 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.

(5) Requirements of Medical Prescription Order for Administration. At a minimum, the medical prescription order from a licensed prescriber must include:

(A) The name of the licensed prescriber issuing or authorizing 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.

(6) Record Keeping.

(A) Pharmacists administering or supervising administration of medication pursuant to this rule shall ensure the following records are manually or electronically maintained separate from the prescription files of a pharmacy for each administration:

1. The name, address, and date of birth of the patient;

2. The date, route, and anatomic site of the administration;

3. The medication name and dose. For vaccines and biologics, the manufacturer, expiration date, and lot number must also be documented and recorded;

4. For vaccines, the name and address of the patient's primary health care provider, as identified by the patient or an indication that a primary health care provider was not provided;

5. The identity of the administering pharmacist, or if applicable, the administering intern pharmacist and his/her supervising pharmacist; and

6. If applicable, the nature of an adverse reaction and who was notified.

(B) All records required by this regulation must be kept by the pharmacist for two (2) years from the date of such record. Except as otherwise required by section (3), records must be kept at the pharmacy where the prescription order is maintained. If not administered on behalf of a pharmacy, records not maintained at a pharmacy may be securely stored at a location designated by the pharmacist. Records maintained at a pharmacy must be 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 must be produced within three (3) business days of a board request.

(7) Notification Requirements. Pharmacists administering or supervising administration of medication under this rule, shall ensure:

(A) The patient's primary health care provider is notified of the following within fourteen (14) days of administering a vaccine:

1. The identity of the patient;

2. The 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) The prescriber is notified within twenty-four (24) hours after learning of an adverse event or reaction experienced by a patient following administration. Notification is mandatory and cannot be waived;

(C) Any notifications required by state and federal law are properly completed and documented; and

(D) Notifications required by this section may be made electronically or in writing or via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Documentation of the required notifications, including the notification date, must be maintained as required by subsection (6)(B) or electronically retrievable at the request of the board or the board's authorized designee.

(8) Notification of Intent Refiling. To continue administration, a Notification of Intent to administer drugs by medical prescription order must be refiled with the board biennially along with the pharmacist's Missouri pharmacist license. To refile, a pharmacist must meet the requirements of subsection (3)(B) above.

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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.*

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**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 .*