



Rules of
Department of Insurance,
Financial Institutions and
Professional Registration
Division 2150—State Board of Registration
for the Healing Arts
Chapter 5—General Rules

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**Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2150—State Board of
Registration for the Healing Arts
Chapter 5—General Rules**

20 CSR 2150-5.020 Nonpharmacy Dispensing

PURPOSE: This rule provides information concerning the general responsibilities of a physician who elects to dispense medications from his/her office or clinic.

(1) Physicians must provide patients the freedom of choice concerning the source of drugs and devices prescribed during the course of the physician/patient relationship. This means that no physician may require, as a condition of the physician/patient relationship, that the patient only receive drugs dispensed directly from the physician's office. By the same token, a physician cannot require any patient to use the services of any particular pharmacy.

(2) Physicians must provide appropriate, direct supervision to personnel employed to assist in the dispensing of drugs and devices from the physician's office. It shall be a violation of this rule for any physician to permit the dispensing of medication from his/her clinic or office when that physician is not present unless another physician duly licensed under the provisions of Chapter 334, RSMo is present.

(3) Physicians who elect to dispense medication must comply with the regulations governing the types of container that may be used to repackage prescription drugs as specified by federal law or rule unless the individual to whom the drug is dispensed gives written authorization for the container to be otherwise.

(4) All drugs dispensed by a physician shall bear a label permanently affixed to the exterior of the drug container which sets forth the following information:

- (A) The date;
- (B) The patient's name;
- (C) Complete directions for usage;
- (D) The physician's name and address; and
- (E) The exact name and strength of the drug dispensed and, in the case of a generic drug, the name of the manufacturer or repackager of the drug. It shall be a violation of this rule for a physician to dispense a generic drug and affix to the label any trade

name or other identification that would serve to misrepresent the source of the drug.

(5) Physicians may dispense only to individuals with whom they have established a physician/patient relationship. It shall be a violation of this rule for a physician to dispense medication at the order of any other physician not registered to practice at that same location.

(6) It is not the intention of this rule to interfere with any recognized system for physician education operated by any accredited medical school located within the borders of Missouri nor is it the intention of this rule to interfere with the individual physician's appropriate use of professional samples nor is it the intention of this rule to interfere in any way with the physician's right to directly administer drugs or medicines to any patient.

(7) Whenever dispensing takes place, appropriate records shall be maintained. These records must be adequate to show the name of the patient, the name and strength of the drug dispensed, the quantity, the dose, etc. A separate log must be maintained for controlled substance dispensing.

AUTHORITY: section 334.125, RSMo 1986. This rule originally filed as 4 CSR 150-5.020. Original rule filed May 11, 1984, effective Sept. 14, 1984. Moved to 20 CSR 2150-5.020, effective Aug. 28, 2006.*

**Original authority: 334.125, RSMo 1959.*

20 CSR 2150-5.025 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 334.125, RSMo 2000 and section 338.010, RSMo Supp. 2007. Emergency rule filed Oct. 24, 2007, effective Nov. 3, 2007, expired April 30, 2008. Original rule filed Oct. 24, 2007, effective May 30, 2008.

20 CSR 2150-5.030 Physical Therapy, Rehabilitation Services, or Both

PURPOSE: This rule provides information concerning the disclosure of a physician's pecuniary interest in a physical therapy or rehabilitation service as directed by section 334.100.2(21), RSMo.

(1) Pursuant to the authority granted in section 334.100.2(21), RSMo, physicians who have a pecuniary interest in physical therapy or rehabilitation service facilities must disclose that interest to patients who are prescribed either physical therapy or rehabilitation services using the following form

Missouri state law, 334.100.2(21), RSMo, requires a physician notify the patient or guardian that the physician has a pecuniary (financial) interest in the physical therapy facility in which prescribed treatment is provided, and that physical therapy or rehabilitation services are available to the patient on a competitive basis from other facilities.

Therefore, I understand that Dr. _____ has a financial interest in _____ facility.

Further, I understand that I have the right to choose any other physical therapy or rehabilitation services which may be more convenient or competitive.

Patient/Guardian Signature

Date

This should be retained in the patient's permanent record.

AUTHORITY: sections 334.100.2(21), RSMo Supp. 1990 and 334.125, RSMo 1986. This rule originally filed as 4 CSR 150-5.030. Original rule filed April 4, 1990, effective Nov. 30, 1990. Moved to 20 CSR 2150-5.030, effective Aug. 28, 2006.*

**Original authority: 334.100.2(21), RSMo 1939, amended 1945, 1959, 1963, 1974, 1976, 1979, 1981, 1983, 1984, 1986, 1987, 1989, 1990 and 334.125, RSMo 1959.*

**20 CSR 2150-5.100 Collaborative Practice**

PURPOSE: This rule defines collaborative practice arrangement terms and delimits geographic areas; methods of treatment; review of services; and drug/device dispensing or distribution pursuant to prescription.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) For the purpose of these rules, the following definitions shall apply:

(A) Advanced practice nurse—A registered professional nurse who is also an advanced practice nurse as defined in section 335.016(2), RSMo;

(B) Collaborative practice arrangements—refers to written agreements, jointly agreed upon protocols, or standing orders, all of which shall be in writing, for the delivery of health care services; and

(C) Registered professional nurse—A registered professional nurse as defined in section 335.016(9), RSMo, who is not an advanced practice nurse.

(2) Geographic Areas.

(A) The collaborating physician in a collaborative practice arrangement shall not be so geographically distanced from the collaborating registered professional nurse or advanced practice nurse as to create an impediment to effective collaboration in the delivery of health care services or the adequate review of those services.

(B) The use of a collaborative practice arrangement by an advanced practice nurse who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons shall be limited to practice locations where the collaborating physician, or other physician designated in the collaborative practice arrangement, is no further than fifty (50) miles by road, using the most direct route available, from the collaborating advanced practice nurse if the advanced prac-

tice nurse is practicing in federally designated health professional shortage areas (HPSAs). Otherwise, in non-HPSAs, the collaborating physician and collaborating advanced practice nurse shall practice within thirty (30) miles by road of one another. The provision of the above specified health care services pursuant to a collaborative practice arrangement shall be limited to only an advanced practice nurse.

(C) An advanced practice nurse who desires to enter into a collaborative practice arrangement to provide health care services that include the diagnosis and treatment of acutely or chronically ill or injured persons at a location where the collaborating physician is not continuously present shall practice at the same location with the collaborating physician for a period of at least one (1) calendar month before the collaborating advanced practice nurse practices at a location where the collaborating physician is not present. The provision of the above specified health care services pursuant to a collaborative practice arrangement shall be limited to only an advanced practice nurse. This provision applies to all collaborative practice arrangements between a physician and an advanced practice nurse unless a waiver is obtained as provided in 20 CSR 2150-5.100(2)(D).

(D) If an advanced practice nurse has been continuously providing health care services pursuant to a collaborative practice arrangement with the same physician for at least one (1) year and the collaborating physician terminates the collaborative practice arrangement with less than thirty (30) days notice for reasons unrelated to the advanced practice nurse, 20 CSR 2150-5.100(2)(C) may be waived by the board of nursing and the board of healing arts if the requirement for one (1) calendar month same-site collaboration would result in health care services at the location where the advanced practice nurse practices being discontinued or reduced. The request for the waiver with supporting documentation shall be submitted to the board of nursing or the board of healing arts by the advanced practice nurse or the collaborating physician and shall specify all information necessary for the board of nursing and the board of healing arts to evaluate the request including, but not limited to, the date and reasons for the termination of the collaborative practice arrangement, number of patients affected and plan for a new collaborative practice arrangement.

(3) Methods of Treatment.

(A) The methods of treatment and the authority to administer, dispense, or pre-

scribe drugs delegated in a collaborative practice arrangement between a collaborating physician and collaborating registered professional nurse or advanced practice nurse shall be within the scope of practice of each professional and shall be consistent with each professional's skill, training, education, and competence.

(B) The collaborating physician shall consider the level of skill, education, training, and competence of the collaborating registered professional nurse or advanced practice nurse and ensure that the delegated responsibilities contained in the collaborative practice arrangement are consistent with that level of skill, education, training, and competence.

(C) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall also be consistent with the scope of practice of the collaborating physician.

(D) Guidelines for consultation and referral to the collaborating physician or designated health care facility for services or emergency care that is beyond the education, training, competence, or scope of practice of the collaborating registered professional nurse or advanced practice nurse shall be established in the collaborative practice arrangement.

(E) The methods of treatment and authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall not be further delegated to any other person except that the individuals identified in sections 338.095 and 338.198, RSMo may communicate prescription drug orders to a pharmacist.

(F) The methods of treatment, including any authority to administer or dispense drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse shall be delivered only pursuant to a written agreement, jointly agreed-upon protocols, or standing orders that shall describe a specific sequence of orders, steps, or procedures to be followed in providing patient care in specified clinical situations.

(G) The methods of treatment, including any authority to administer, dispense, or prescribe drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating advanced practice nurse shall be delivered only pursuant to a written agreement, jointly agreed upon protocols, or standing orders that are specific to



the clinical conditions treated by the collaborating physician and collaborating advanced practice nurse.

(H) The collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse or advanced practice nurse shall be signed and dated by the collaborating physician and collaborating registered professional nurse or advanced practice nurse before it is implemented, signifying that both are aware of its content and agree to follow the terms of the collaborative practice arrangement. The collaborative practice arrangement and any subsequent notice of termination of the collaborative practice arrangement shall be in writing and shall be maintained by the collaborating professionals for a minimum of eight (8) years after termination of the collaborative practice arrangement. The collaborative practice arrangement shall be reviewed and revised as needed by the collaborating physician and collaborating registered professional nurse or advanced practice nurse.

(I) Methods of treatment delegated and authority to administer, dispense, or prescribe drugs shall be subject to the following:

1. The physician retains the responsibility for ensuring the appropriate administering, dispensing, prescribing and control of drugs utilized pursuant to a collaborative practice arrangement in accordance with all state and federal statutes, rules, or regulations;

2. All labeling requirements outlined in section 338.059, RSMo shall be followed;

3. Consumer product safety laws and Class B container standards shall be followed when packaging drugs for distribution;

4. All drugs shall be stored according to the *United States Pharmacopeia* (USP) recommended conditions, which is incorporated by reference;

5. Outdated drugs shall be separated from the active inventory;

6. Retrieval dispensing logs shall be maintained for all prescription drugs dispensed and shall include all information required by state and federal statutes, rules, or regulations;

7. All prescriptions shall conform to all applicable state and federal statutes, rules, or regulations and shall include the name, address, and telephone number of the collaborating physician and collaborating advanced practice nurse;

8. A registered professional nurse shall not, under any circumstances, prescribe drugs;

9. An advanced practice nurse shall not, under any circumstances, prescribe controlled substances. The administering or dis-

persing of a controlled substance by a registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be accomplished only under the direction and supervision of the collaborating physician, or other physician designated in the collaborative practice arrangement, and shall only occur on a case-by-case determination of the patient's needs following verbal consultation between the collaborating physician and collaborating registered professional nurse or advanced practice nurse. The required consultation and the physician's directions for the administering or dispensing of controlled substances shall be recorded in the patient's chart and in the appropriate dispensing log. These recordings shall be made by the collaborating registered professional nurse or advanced practice nurse and shall be cosigned by the collaborating physician following a review of the records;

10. An advanced practice nurse or registered professional nurse in a collaborative practice arrangement may only dispense starter doses of medication to cover a period of time for seventy-two (72) hours or less with the exception of Title X family planning providers or publicly funded clinics in community health settings that dispense medications free of charge. The dispensing of drug samples, as defined in 21 U.S.C. section 353 (c)(1), is permitted as appropriate to complete drug therapy; and

11. The medications to be administered, dispensed, or prescribed by a collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be consistent with the education, training, competence, and scopes of practice of the collaborating physician and collaborating registered professional nurse or advanced practice nurse.

(J) When a collaborative practice arrangement is utilized to provide health care services for conditions other than acute self-limited or well defined problems, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall see the patient for evaluation and approve or formulate the plan of treatment for new or significantly changed conditions as soon as is practical, but in no case more than two (2) weeks after the patient has been seen by the collaborating advanced practice nurse or registered professional nurse.

(K) Nothing in these rules shall be construed to permit medical diagnosis of any condition by a registered professional nurse pursuant to a collaborative practice arrange-

(4) Review of Services.

(A) In order to assure true collaborative practice and to foster effective communication and review of services, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall be immediately available for consultation to the collaborating registered professional nurse or advanced practice nurse at all times, either personally or via telecommunications.

(B) The collaborating physician shall review the work, records, and practice of the health care delivered pursuant to a collaborative practice arrangement at least once every two (2) weeks. This review shall be documented by the collaborating physician. This subsection shall not apply to the situation described in subsection (4)(E) below or during the time the collaborating physician and collaborating advanced practice nurse are practicing together as required in subsection (2)(C) above.

(C) If a collaborative practice arrangement is used in clinical situations where a collaborating advanced practice nurse provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons, then the collaborating physician shall be present for sufficient periods of time, at least once every two (2) weeks, except in extraordinary circumstances that shall be documented, to participate in such review and to provide necessary medical direction, medical services, consultations, and supervision of the health care staff. In such settings the use of a collaborative practice arrangement shall be limited to only an advanced practice nurse and the physician shall not enter into a collaborative practice arrangement with more than three (3) full-time equivalent advanced practice nurses.

(D) The collaborating physician and collaborating registered professional nurse or advanced practice nurse shall determine an appropriate process of review and management of abnormal test results which shall be documented in the collaborative practice arrangement.

(E) In the case of collaborating physicians and collaborating registered professional nurses or advanced practice nurses practicing in settings which provide care to well patients or to those with narrowly circumscribed conditions in public health clinics or community health settings that provide population-based health services limited to immunizations, well child care, human immunodeficiency virus (HIV) and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease and wellness screenings, services related to



epidemiologic investigations and prenatal care, review of services shall occur as needed and set forth in the collaborative practice arrangement. If the services provided in such settings include diagnosis and the initiation of treatment of any other disease or injury, then the provisions of subsection (4)(C) shall apply.

(F) The process and documentation of review shall be on file and maintained in the collaborative practice setting.

(G) The State Board of Registration for the Healing Arts and the State Board of Nursing separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licensee's participation in a collaborative practice arrangement.

(5) Population-Based Public Health Services.

(A) In the case of the collaborating physicians and collaborating registered professional nurses or advanced practice nurses practicing in association with public health clinics that provide population-based health services limited to immunizations, well child care, HIV and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease and wellness screenings, services related to epidemiologic investigations and related treatment, and prenatal care, the geographic areas, methods of treatment and review of services shall occur as set forth in the collaborative practice arrangement. If the services provided in such settings include diagnosis and initiation of treatment of disease or injury not related to population-based health services, then the provisions of sections (2), (3), and (4) above shall apply.

AUTHORITY: sections 334.104.3 and 335.036, RSMo Supp. 2007 and section 334.125, RSMo 2000. This rule originally filed as 4 CSR 150-5.100. Original rule filed Jan. 29, 1996, effective Sept. 30, 1996. Amended: Filed April 1, 1998, effective Oct. 30, 1998. Amended: Filed Oct. 30, 2002, effective June 30, 2003. Moved to 20 CSR 2150-5.100, effective Aug. 28, 2006. Amended: Filed Dec. 14, 2007, effective June 30, 2008.*

**Original authority: 334.104.3, RSMo 1993 amended 2002, 2003, 2006; 334.125, RSMo 1959, amended 1993, 1995; and 335.036, RSMo 1975, amended 1981, 1985, 1993, 1995, 1999, 2007.*