# 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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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 supervision to personnel employed to assist in the dispensing of drugs and devices from the physician’s office.

(A) When the dispensing personnel is either a licensed physician assistant acting within the scope of a supervision agreement or licensed nurse acting within the scope of a collaborative practice arrangement, the physician is not required to be present.

(B) In all other instances, 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 repackaged 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.


20 CSR 2150-5.025 Administration of Vaccines Per Protocol

PURPOSE: This rule establishes the procedures for pharmacists to administer vaccines per written protocol with a physician.

(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 with manufacturer’s guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (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 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 vaccines.

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

(4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:

(A) Hold a current, unrestricted license to practice pharmacy in this state;
(B) Hold a current 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 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 per calendar year related to administration of vaccines. 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 vaccines; and
(G) On a yearly basis prior to administering 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) 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 vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. 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 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 vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized 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 addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
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.

(6) Record Keeping.

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall 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 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 subsection (6)(A) of this rule are promptly delivered to the pharmacy.

(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; and
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 State Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(7) Notification Requirement.

(A) A pharmacist administering 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 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 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.


20 CSR 2150-5.300 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.


20 CSR 2150-5.100 Collaborative Practice

PURPOSE: In accordance with section 334.104, RSMo, 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. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

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

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

(B) Controlled substance prescriptive authority—the eligibility and certificate granted by the Missouri State Board of Nursing (MSBN) to an APRN who has been delegated the authority to prescribe controlled substances from Schedules III, IV, and/or V in a written collaborative practice arrangement by the collaborating physician as defined in section 335.019, RSMo;

(C) 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;

(D) Population-based public health services—Health services provided to well patients or to those with narrowly circumscribed conditions in public health clinics or community health settings that are limited to immunizations, well child care, human immunodeficiency virus (HIV) and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease, wellness screenings, services related to epidemiologic investigations, and prenatal care; and

(E) Registered professional nurse—An RN as defined in section 335.016(16), RSMo, who is not an APRN.

(2) Geographic Areas.

(A) The collaborating physician in a collaborative practice arrangement shall not be so geographically distanced from the collaborating RN or APRN 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 APRN 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 APRN if the APRN is practicing in federally-designated health professional shortage areas (HPSAs). Otherwise, in non-HPSAs, the collaborating physician and collaborating APRN shall practice within thirty (30) miles by road of one another.

(C) An APRN who desires to enter into a collaborative practice arrangement at a location where the collaborating physician is not continuously present shall practice together at the same location with the collaborating physician continuously present for a period of at least one (1) month before the collaborating APRN practices at a location where the collaborating physician is not present. It is the responsibility of the collaborating physician to determine and document the completion of the same location practice described in the previous sentence.

(D) A collaborating physician shall not enter into a collaborative practice arrangement with more than three (3) full-time equivalent APRNs. This limitation shall not apply to collaborative arrangements of hospital employees providing inpatient care services in hospitals as defined in Chapter 197, RSMo, or population-based public health services as defined in this rule.

(3) Methods of Treatment.

(A) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated in a collaborative practice arrangement between a collaborating physician and collaborating APRN shall be within the scope of practice of each professional and shall be consistent with each professional’s skill, training, education, competence, licensure, and/or certification and shall not be further delegated to any person except that the individuals identified in sections 338.095 and 338.198, RSMo, may communicate prescription drug orders to a pharmacist.

(B) The methods of treatment and authority to administer and dispense drugs delegated in a collaborative practice arrangement between a collaborating physician and a collaborating RN shall be within the scope of practice of each professional and shall be consistent with each professional’s skill, training, education, competence and shall not be delegated to any person except the individuals identified in sections 338.095 and 338.198, RSMo, may communicate prescription drug orders to a pharmacist.

(C) The collaborating physician shall consider the level of skill, education, training, and competence of the collaborating RN or APRN and ensure that the delegated responsibilities contained in the collaborative practice arrangement are consistent with that level of skill, education, training, and competence.

(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 RN or APRN shall be established in the collaborative practice arrangement.

(E) 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 RN 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.

(F) The methods of treatment, including authority to administer, dispense, or prescribe drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating APRN 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 APRN.

(G) 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), (2010), published by the United States Pharmacopoeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852-1790, 800-227-8772; http://www.usp.org/ recommended conditions, which is incorporated by reference. This does not include any later amendments or additions;

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

6. Retrievable 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 APRN;

8. An RN shall not, under any circumstances, prescribe drugs. The administering or dispensing of a controlled substance by an RN or APRN who has not been delegated authority to prescribe in a collaborative practice arrangement, pursuant to 19 CSR 30-1.066, 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 RN or APRN. 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 RN or APRN and shall be signed by the collaborating physician following a review of the records;

9. In addition to administering and dispensing controlled substances, an APRN, as defined in section 335.016, RSMo, may be delegated the authority to prescribe controlled substances listed in Schedules III, IV, and V of section 195.017, RSMo, in a written collaborative practice arrangement, except that, the collaborative practice arrangement shall not delegate the authority to administer any controlled substances listed in Schedules III, IV, and V of section 195.017, RSMo, for the purpose of inducing sedation or general anesthesia for therapeutic, diagnostic, or surgical procedures. Schedule III narcotic controlled substance prescriptions shall be limited to a one hundred twenty (120)-hour supply without refill;

10. An APRN may not prescribe controlled substances for his or her own self or family. Family is defined as spouse, parents, grandparents, great-grandparents, children, grandchildren, great-grandchildren, brothers and sisters, aunts and uncles, nephews and nieces, mother-in-law, father-in-law, brothers-in-law, sisters-in-law, daughters-in-law, and sons-in-law. Adopted and step members are also included in family;

11. An APRN or RN 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;

12. The collaborative practice arrangement shall clearly identify the controlled substances the collaborating physician authorizes the collaborating APRN to prescribe and document that it is consistent with each professional’s education, knowledge, skill, and competence; and

13. The medications to be administered, dispensed, or prescribed by a collaborating RN or APRN in a collaborative practice arrangement shall be consistent with the education, training, competence, and scopes of practice of the collaborating physician and collaborating RN or APRN.

(H) 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 examine and evaluate the patient and approve or formulate the plan of treatment for new or significantly changed conditions as soon as practical, but in no case more than two (2) weeks after the patient has been seen by the collaborating APRN or RN.

(I) Nothing in these rules shall be construed to permit medical diagnosis of any condition by an RN pursuant to a collaborative practice arrangement.

(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 RN or APRN at all times, either personally or via telecommunications.

(B) The collaborative practice arrangement between a collaborating physician and a collaborating RN or APRN shall be signed and dated by the collaborating physician and collaborating RN or APRN 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 at least annually and revised as needed by the collaborating physician and collaborating RN or APRN. Documentation of the annual review shall be maintained as part of the collaborative practice arrangement.

(C) Within thirty (30) days of any change and with each physician’s license renewal, the collaborating physician shall advise the Missouri State Board of Registration for the
Healing Arts whether he/she is engaged in any collaborative practice agreement, including collaborative practice agreements delegating the authority to prescribe controlled substances and also report to the board the name of each licensed RN or APRN with whom he/she has entered into such agreement. A change shall include, but not be limited to, resignation or termination of the RN or APRN; change in practice locations; and addition of new collaborating professionals.

(D) An RN or an APRN practicing pursuant to a collaborative practice arrangement shall maintain adequate and complete patient records in compliance with section 334.097, RSMo.

(E) The collaborating physician shall complete a review of a minimum of ten percent (10%) of the total health care services delivered by the collaborating APRN. If the APRN’s practice includes the prescribing of controlled substances, the physician shall review a minimum of twenty percent (20%) of the cases in which the APRN wrote a prescription for a controlled substance. If the controlled substance chart review meets the minimum total ten percent (10%) as described above, then the minimum review requirements have been met. The collaborating APRN’s documentation shall be submitted for review to the collaborating physician at least every fourteen (14) days. This documentation submission may be accomplished in person or by other electronic means and reviewed by the collaborating physician. The collaborating physician must produce evidence of the chart review upon request of the Missouri State Board of Registration for the Healing Arts. This subsection shall not apply during the time the collaborating physician and collaborating APRN are practicing together as required in subsection (2)(C) above.

(F) If a collaborative practice arrangement is used in clinical situations where a collaborating APRN 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 APRN.

(G) The collaborating physician and collaborating RN or APRN shall determine an appropriate process of review and management of abnormal test results which shall be documented in the collaborative practice arrangement.

(H) The Missouri State Board of Registration for the Healing Arts and the Missouri 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 APRN practicing in association with public health clinics that provide population-based health services as defined in section (1) of this rule, 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.
