RULES OF

Department of Commerce and Insurance

Division 2150—State Board of Registration for the Healing Arts

Chapter 5—General Rules

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TITLE 20 — DEPARTMENT OF COMMERCE AND INSURANCE
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 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 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 2000. 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. Amended: Filed Aug. 14, 2009, effective Jan. 30, 2010.*

**Original authority: 334.125, RSMo 1959, amended 1993, 1995.*

20 CSR 2150-5.024 HIV Post-Exposure Prophylaxis

PURPOSE: This rule establishes requirements for authorized pharmacists dispensing HIV post-exposure prophylaxis as authorized by section 338.730, RSMo.

(1) Definitions.

(A) Authorized pharmacist — A Missouri-licensed pharmacist who has completed a training course or certificate program in HIV antiretroviral prophylaxis that includes training in CDC guidelines for HIV PEP.

(B) Authorizing physician — A physician identified in a written protocol as authorizing a pharmacist to dispense HIV PEP and who will be collaborating with an authorized pharmacist in HIV PEP dispensing.

(C) CDC guidelines — The current human immunodeficiency virus (HIV) guidelines published by the federal Centers for Disease Control and Prevention (CDC) for non-occupational and occupational HIV exposure.

(D) Medical staff committee — The medical staff committee of a hospital or hospital system as defined by section 338.165, RSMo, that includes a Missouri-licensed physician, or the medical staff committee or similar body of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician and is responsible for formulating policies regarding pharmacy services and medication management for the long-term care facility.

(E) Pharmacy resident — A graduate of a pharmacy school/college accredited by the Accreditation Council for Pharmacy Education (ACPE) who is a licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists, a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists, or a residency program operated by or in conjunction with an ACPE-accredited school or college of pharmacy.

(F) Physician — An individual who is actively engaged in the practice of medicine in the state of Missouri and holds a current Missouri physician and surgeon license pursuant to Chapter 334, RSMo, which is not encumbered in any way, such as by designation as probated, restricted, limited, temporary, inactive, or retired;

(G) Post-exposure prophylaxis (PEP) — Any medication approved by the Food and Drug Administration (FDA) that meets the same clinical eligibility recommendations provided in CDC guidelines.

(H) Protocol – For purposes of section 338.730, RSMo, and this rule, a protocol is defined as –

1. A written protocol approved by a Missouri-licensed physician that meets the minimum standards in section (2) of this rule and agreed to by the authorized pharmacist who would be dispensing HIV PEP;

2. A written protocol approved by the medical staff committee of a hospital or hospital system as defined by section 338.165, RSMo, that includes a Missouri-licensed physician;

3. A written protocol approved by the medical staff committee of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician; or

4. A standing order issued by the Director of the Missouri Department of Health and Senior Services (DHSS) if a physician, or by a physician approved and designated by DHSS.

(2) Authorized pharmacists may enter a written protocol to prescribe and dispense HIV PEP, as provided by section 338.730, RSMo. HIV PEP protocols must be within the skill, education, training, and competence of both the authorizing physician and authorized pharmacist.

(A) HIV PEP protocols must adhere to CDC guidelines and include specific directions for the authorized pharmacist to follow. Except as otherwise provided by DHSS for a DHSS protocol, HIV PEP protocols must, at a minimum, include the following:

1. Directions/guidelines for patient assessment and counseling;

2. Authorized drug therapies to be dispensed, including the specified dosage regimen and dosage forms;

3. Authorized route(s) of administration;

4. Specific requirements for referring patients to a healthcare provider for additional evaluation/treatment;

5. Any patient counseling requirements designated by the authorizing physician; and

6. Any documentation or recordkeeping required by the authorizing physician.

(B) Protocols may include provisions that allow an authorized pharmacist to create a prescription in the physician's name for HIV PEP medication. The prescription must comply with all applicable state and federal law. The prescription may be dispensed by a licensed pharmacy and must be maintained in the prescription records of the dispensing pharmacy as provided by the Missouri State Board of Pharmacy's rules.

(C) Protocols may allow the authorized pharmacist to order or perform testing as authorized by the protocol physician or medical staff committee. If the protocol includes conducting physical assessments or ordering and evaluating laboratory or other tests, the protocol must identify required assessments, authorized tests to be ordered, the criteria for ordering the assessments and tests, interpretation of assessments/tests, and what action the authorized pharmacist is authorized to take based on assessment/test results.

(D) Except as otherwise authorized for a DHSS statewide standing order, protocols must be signed and dated by the authorizing physician and the authorized pharmacist. If the protocol includes multiple physicians or authorized pharmacists, a separate protocol is not required for each physician or authorized pharmacist if all authorizing physicians and authorized pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol. Unless otherwise required by DHSS, a HIV PEP statewide standing order is exempt from the signature/dating requirements of this subsection. When utilizing the HIV PEP statewide standing order issued by DHSS, the pharmacist or the designee of the pharmacist shall periodically review the HIV PEP statewide standing order and ensure it is current and active.

(E) Pharmacy residents. In lieu of an individual protocol, a pharmacy resident may dispense HIV PEP as part of their residency training under the HIV PEP protocol of an authorized pharmacist, if authorized by the governing protocol.

(F) Protocols must be physically or electronically maintained by both the authorizing physician and authorized pharmacist and available to the Board of Pharmacy and the Board of Registration for the Healing Arts for a minimum of eight (8) years after termination of the protocol.

(G) DHSS protocols shall be governed by and comply with all DHSS requirements and provisions.

(3) Compliance and Supervision.

(A) Authorized pharmacists must ensure patient care activities are safely and properly performed in accordance with the governing protocol, recognized standards of practice, and current CDC guidelines. Additionally, authorized pharmacists must comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and recordkeeping.

(B) The authorizing physician shall be responsible for overseeing compliance with protocol requirements, section 338.730, RSMo, and current CDC guidelines, but may designate such responsibilities to a pharmacist if a medication therapy services protocol is in place that includes dispensing HIV PEP. Except as otherwise provided by a DHSS protocol, the authorizing physician or a designee of the authorizing physician who is a Missouri-licensed healthcare provider must be available to –

1. Provide follow-up appointments for care of patients who received PEP pursuant to a HIV PEP protocol, or maintain a list of physician, surgeons, clinics, or other Missouri-licensed healthcare providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept referrals of patients within a reasonable time of the authorized pharmacist initiating HIV PEP and deliver care; and

2. Respond to calls/inquiries from the authorized pharmacist regarding HIV PEP dispensing, treatment, or patient assessment.

(4) Authorized pharmacists prescribing/dispensing HIV PEP pursuant to a DHSS standing order must comply with all DHSS requirements. Authorized pharmacists must comply with the following requirements when prescribing/dispensing HIV PEP based on all other protocols:

(A) Unless otherwise provided by CDC guidelines or restricted by the governing protocol, an authorized pharmacist may dispense a twenty-eight- (28-) day course of HIV PEP therapy, if all of the following conditions are met:

1. The patient is thirteen (13) years of age or older;

2. The patient is HIV negative, as documented by a negative HIV test result obtained within the previous twenty-four (24) hours from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the authorized pharmacist shall order an HIV test. If the test results are not transmitted directly to the authorized pharmacist, the pharmacist shall verify the test results to the authorized pharmacist's satisfaction. If the patient tests positive for HIV infection, the authorized

pharmacist must immediately notify the patient and refer the patient to the patient's primary care provider if known, and provide a list of providers and clinics in the patient's region for confirmatory testing and follow-up care. If an HIV test is not reasonably available for twenty-four (24) hours or longer, the authorized pharmacist may use clinical discretion to dispense HIV PEP upon verification that other criteria for dispensing has been met and HIV PEP is otherwise indicated;

3. The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms;

4. The patient is not taking any contraindicated medications per guidelines and package insert information;

5. The single high-risk event of non-occupational exposure to HIV occurred within seventy-two (72) hours of the pharmacist-patient encounter; and

6. An authorized pharmacist may not dispense HIV PEP to an individual patient by protocol more than twice every three hundred sixty-five (365) days. The authorized pharmacist must notify the patient of the three hundred sixty-five- (365-) day limit and advise the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for PEP if the patient exceeds the three hundred sixty-five- (365-) day dispensing limit;

(B) Authorized pharmacists must counsel patients on the safe and appropriate use of HIV PEP to maximize therapeutic outcomes. Counseling may include, but is not limited to, education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity. The authorized pharmacist should stress the importance of ongoing monitoring and follow-up care with a primary care provider, and recommend routine primary care and health maintenance. Authorized pharmacists must also notify patients that confirmation HIV testing is recommended at three (3) and six (6) months or the interval(s) recommended by the CDC;

(C) Because of the importance of follow-up care and the potential difficulty of obtaining an appointment on short notice, authorized pharmacists must provide patients prescribed or dispensed HIV PEP a list of, and addresses and contact information for, nearby federally qualified health centers, local county health departments, hospitals, emergency departments, or other governmental providers/agencies that may provide follow-up care or HIV testing, treatment, or counseling for the patient; and

(D) The authorized pharmacist must notify the patient's primary care provider when the pharmacist prescribes/dispenses HIV PEP to the patient. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the authorized pharmacist must provide the patient a list of physicians and surgeons, clinics, or other healthcare service providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept new or uninsured patients and deliver care in a timely fashion. The required list must be developed in consultation with or approved by the authorizing physician, and must be updated by December 31 of each calendar year and as needed to ensure patients have access to follow-up care and success with obtaining appointments. If the patient does not have a primary care provider, the authorized pharmacist must also recommend that the patient use a patient healthcare navigator or community healthcare case worker as defined by the CDC to access healthcare services. An authorized pharmacist must document authorization from the patient prior to facilitating referrals, coordinating follow-up care, or making appointments with a provider on the patient's behalf.

(5) Mandatory Referrals/Reporting. Authorized pharmacists must make the following referrals when prescribing/dispensing HIV PEP by protocol:

(A) An authorized pharmacist shall not prescribe or dispense HIV PEP and must immediately refer the patient to an emergency department or a primary care provider for urgent treatment if the patient is under thirteen (13) years old or is taking any contraindicated medications per guidelines and package insert information;

(B) If a patient tests positive for HIV infection, a sexually transmitted disease, or hepatitis B or C, the authorized pharmacist must refer or direct the patient to a primary care provider and provide the patient a list of providers or clinics in the patient's region for confirmatory testing and follow-up care;

(C) If the patient returns to the authorized pharmacist for follow-up care and shows signs or symptoms of acute renal injury, acute HIV infection, acute drug toxicities, or serious side effects after taking HIV PEP, the authorized pharmacist shall immediately refer the patient to an emergency department for urgent evaluation and treatment; and

(D) Authorized pharmacists shall report actual or suspected child abuse or neglect to the Missouri Department of Social Services, Children's Division, as required by Missouri law, including but not limited to sections 210.115 and 210.130, RSMo. If the case involves a known sexual assault victim, the authorized pharmacist shall refer the patient to an emergency department, and recommend that the patient contact law enforcement and be examined and co-managed by professionals trained in assessing and counseling individuals who have been sexually assaulted.

(6) Patient Medical Records. Authorized pharmacists shall maintain a patient medical record for each patient that documents the care provided for the patient pursuant to a HIV PEP protocol.

(A) At a minimum, the required patient medical record must include:

1. The patient's name, birthdate, address, and telephone number;

2. The date(s) the patient was seen;

3. The name or identity of the authorized pharmacist;

4. The patient's primary care provider, if provided;

5. Documentation of patient screening;

6. All information required by the governing protocol or requested by the authorizing physician;

7. Any other pertinent medical or medication information/history;

8. The name and dosage of medication dispensed or prescribed under the authorizing physician's name; and

9. Any healthcare provider referrals.

(B) Patient medical records must be individually retrievable and must be securely and confidentially maintained in compliance with applicable state and federal law. At a minimum, patient medical records must be maintained for seven (7) years from the date created. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from a board or a board's authorized designee. Records not maintained at a pharmacy must be

produced within three (3) business days of a board request.

(C) Patient records for pharmacy services provided by an authorized pharmacist pursuant to an HIV PEP protocol must be produced to the authorizing physician or medical staff committee on request.

(7) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board's designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

AUTHORITY: section 334.125, RSMo 2016, and section 338.730, RSMo Supp. 2022. Original rule filed Aug. 10, 2022, effective Feb. 28, 2023.*

**Original authority: 334.125, RSMo 1959, amended 1993, 1995, 2014, and 338.730, RSMo 2021.*

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 with a Missouri licensed physician who is actively engaged in the practice of medicine. Unless otherwise restricted by the governing protocol, vaccines may be administered at any Missouri licensed pharmacy or at any non-pharmacy location as allowed in the governing protocol.

(A) Vaccines must be administered in accordance with current treatment guidelines established by the Centers for Disease Control (CDC) and the manufacturer's guidelines, provided CDC guidelines shall control in the event of a conflict. Vaccines may not be administered to persons under seven (7) years of age unless otherwise authorized by law.

(B) Pharmacists shall ensure compliance with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) Vaccines must be stored in accordance with CDC guidelines/recommendations and within the manufacturer's labeled requirements, including, when vaccinating outside of a pharmacy.

(D) A pharmacist may only delegate vaccine administration to an intern pharmacist or qualified pharmacy technician who has met the qualifications of subsections (3)(B) and (C) of this rule and is working under the direct supervision of a pharmacist qualified to administer vaccines. Proof of an intern's or qualified pharmacy technician's compliance with subsections (3)(B) and (C) must be maintained by both the supervising pharmacist and the intern pharmacist/qualifying pharmacy technician for a minimum of two (2) years.

(E) For purposes of this rule, a "qualified pharmacy technician" is defined as a currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Has an initial and, if applicable, annual documented assessment of competency in vaccine administration; and

3. Has assisted in the practice of pharmacy as a registered/licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year.

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

(3) Pharmacist Qualifications. Pharmacists administering vaccines by protocol as authorized by Chapter 338, RSMo, must first file a Notification of Intent (NOI) to administer vaccines with the Missouri Board of Pharmacy. To file a NOI, a pharmacist must –

(A) Hold a current Missouri pharmacist license;

(B) Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification issued by the American Heart Association, the American Red Cross, or an equivalent organization. The qualifying BLS or CPR certification program must have included a live in-person skills assessment; and

(C) Have successfully completed a certificate program in administering vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE, or regionally accredited pharmacy or medical school/college or approved by the Board of Pharmacy. The required certificate program must include a live/in-person training component and include instruction in:

1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including, recommended immunization schedules;

2. Basic immunology and vaccine protection;

3. Physiology and techniques for vaccine administration, including, hands-on training in intramuscular, intradermal, subcutaneous and nasal administration routes, and other common routes of vaccine administration;

4. Pre- and post- vaccine screening or assessment; and

5. Identifying and treating adverse immunization reactions;

(D) Notifications of Intent must be filed on the board's website or on a form approved by the board.

(4) Protocol Requirements.

(A) In addition to filing a NOI, pharmacists administering vaccines under this rule must first enter into a written protocol with a Missouri licensed physician. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must be renewed annually and include the following:

1. The identity of the participating pharmacist and physician;

2. Time period of the protocol;

3. Authorized vaccines;

4. The patient or groups of patients authorized for vaccination;

5. Allowed routes and anatomic sites of administration;

6. If applicable, authorization to create a prescription for each administration under the physician's name;

7. Emergency response procedures, including, but not limited to, procedures for handling/addressing adverse reactions, anaphylactic reactions, and accidental needle sticks;

8. The length of time the pharmacist must observe an individual for adverse events following an injection;

9. Procedures for disposing of used and contaminated supplies;

10. Authorization to administer vaccines at a non-pharmacy location, if applicable;

11. Record-keeping requirements and any required notification procedures; and

12. A provision allowing termination of the protocol at any time at the request of any party.

(B) The protocol, and any subsequent amendments or alterations, must be reviewed and manually or electronically signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its contents and agree to follow the terms of the protocol. A copy of the protocol must be maintained by both the pharmacist and the authorizing physician for a minimum of eight (8) years after termination of the protocol.

(C) Additional pharmacists or immunization locations may be added to an existing protocol if the amendment is signed and dated by the authorizing physician(s) and, if applicable, any newly added pharmacist(s). Existing pharmacists are not required to re-sign the protocol unless other protocol terms or provisions are changed.

(5) Record Keeping.

(A) The pharmacist shall ensure a record is maintained for each vaccine administered by protocol that includes:

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

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

3. The vaccine's name, dose, manufacturer, lot number, and expiration date;

4. The name and address of the patient's primary health care provider, as provided by the patient;

5. The identity of the administering pharmacist or, if applicable, the identity of the administering intern pharmacist or qualified pharmacy technician and supervising pharmacist; and

6. The nature of any adverse reaction and who was notified, if applicable.

(B) Within seventy-two (72) hours after a vaccine is administered, a prescription must be obtained from the authorizing physician for the drug dispensed or a prescription must be created in the physician's name documenting the dispensing as authorized by protocol. Notwithstanding any other provision of this rule, prescription records must be maintained as provided by Chapter 338, RSMo, and the rules of the board.

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

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure the records required by subsection (5)(A) are promptly delivered to and maintained at the pharmacy separate from the pharmacy's prescription files;

2. If the vaccine is not administered on behalf of a pharmacy, records must be maintained by the administering or supervising pharmacist at an address identified in the protocol prior to administering the vaccine;

3. Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the board; and

4. Records required by this rule must be maintained for two (2) years and 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 must be produced within three (3) business days after a request from the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(6) Notification of Immunizations. Pharmacists immunizing by protocol must –

(A) Notify all persons or entities as required by state and federal law;

(B) Notify the protocol physician as required by the governing protocol;

(C) Notify the patient's primary care provider as required by Chapter 338, RSMo; and

(D) Notify the patient's primary health care provider and, if different, the protocol physician, within twenty-four (24) hours after learning of any adverse event or reaction experienced by the patient. Adverse events or reactions must also be reported to the Vaccine Adverse Event Reporting System (VAERS) or its successor, within thirty (30) days.

(E) Unless otherwise provided by the governing protocol, notification may be made via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Proof of notification must be maintained in the pharmacist's records as provided in subsection (5)(C) of this rule.

(7) Notification of Intent Renewal. A Notification of Intent (NOI) to immunize by protocol must be renewed biennially with the immunizing pharmacist's Missouri pharmacist license. To renew a NOI, pharmacists must –

(A) Have a current healthcare provider cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification that complies with subsection (3)(B) of this rule; and

(B) Have completed a minimum of two (2) hours of continuing education (0.2 CEU) related to administering vaccines or CDC immunization guidelines in a course approved by the Board of Pharmacy or provided by an ACPE accredited continuing education provider within the applicable pharmacist biennial renewal period (November 1 to October 31 of the immediately preceding even numbered years).

(C) The required continuing education (CE) shall be governed by 20 CSR 2220-7.080 and may be used to satisfy the pharmacist's biennial continuing education requirements. The initial training program required by section (3) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within the applicable pharmacist biennial renewal cycle.

(8) A qualified pharmacy technician immunizing pursuant to this rule must be supervised by a Missouri-licensed pharmacist who is authorized to immunize by protocol and who is physically present on-site when the vaccine is administered.

AUTHORITY: section 334.125, RSMo 2016, and sections 338.010 and 338.220, RSMo Supp. 2020. Emergency rule filed Oct. 24, 2007, effective Nov. 3, 2007, expired April 30, 2008. Original rule filed Oct. 24, 2007, effective May 30, 2008. Emergency amendment filed Oct. 22, 2009, effective Nov. 1, 2009, expired April 29, 2010. Amended: Filed Oct. 22, 2009, effective June 30, 2010. Emergency amendment filed Aug. 20, 2018, effective Sept. 30, 2018, expired March 28, 2019. Amended: Filed Aug. 20, 2018, effective Feb. 28, 2019. Emergency amendment filed Jan. 4, 2021, effective Jan. 19, 2021, expired July 17, 2021. Amended: Filed Jan. 4, 2021, effective July 30, 2021.*

**Original authority: 334.125, RSMo 1959, amended 1993, 1995, 2014; 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020.*

20 CSR 2150-5.026 General Provisions

PURPOSE: This rule establishes definitions for 20 CSR 2150-5.026 to 20 CSR 2150-5.028 governing medication therapy services by pharmacists.

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2150-5.026 to 20 CSR 2150-5.028:

(A) Authorizing physician(s) – The physician identified in the written protocol as authorizing the pharmacist to provide medication therapy services;

(B) Health care entity – For purposes of this rule, a health care entity shall be defined as any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility, or a habilitation center as defined by Chapter 630, RSMo, and that is required to maintain patient medical records by state or federal law;

(C) Medication therapy protocol – A written agreement between a physician and a pharmacist for the provision of medication therapy services. A medication therapy protocol shall comply with the provisions of 20 CSR 2150-5.028;

(D) Medication therapy services – The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2150-5.026 to 20 CSR 2150-5.028, modification shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication therapy management that does not include the initiation or implementation of a modification of medication therapy, as provided herein;

(E) Pharmacy resident – A Missouri licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists;

(F) Prescription order for medication therapeutic plan – A lawful order that is issued by the authorizing physician within the scope of his/her professional practice for the provision of medication therapy services by a pharmacist for a specific patient, including, patients of a health care entity; and

(G) Protocol – A medication therapy protocol, as defined herein.

(2) The provisions of 20 CSR 2150-5.026 to 20 CSR 2150-5.028 and 20 CSR 2220-6.060 to 20 CSR 2220-6.080 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy, as established by Chapter 334, RSMo, and Chapter 338, RSMo.

AUTHORITY: section 334.125, RSMo 2000, and sections 338.010 and 338.220, RSMo Supp. 2011. Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.*

**Original authority: 334.125, RSMo 1959, amended 1993, 1995; 338.010, RSMo 1939, amended 1989, 1990, 2007, 2009, 2011; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011.*

20 CSR 2150-5.028 Medication Therapy Services By Protocol

PURPOSE: This rule establishes procedures for the provision of medication therapy services by protocol, as authorized by section 338.010, RSMo.

(1) Except as otherwise provided herein, a pharmacist who holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy shall be authorized to provide medication therapy services in Missouri if the pharmacist –

(A) Holds a current Missouri pharmacist license that is not under discipline with the Missouri State Board of Pharmacy; and

(B) Has entered into a written protocol with a Missouri licensed physician that complies with the requirements of this rule.

(2) General Requirements. A pharmacist may provide medication therapy services only with current certification and as authorized by the protocol and the authorizing physician. A pharmacist providing medication therapy services pursuant to this rule shall comply with the following:

(A) Prior to providing medication therapy services, the pharmacist shall receive a prescription order for a medication therapeutic plan from the authorizing physician for a specific patient which authorizes the pharmacist to perform medication therapy services. Except as otherwise provided in subsection (2)(B) of this rule, the prescription order for a medication therapeutic plan shall be valid for no more than one (1) year and shall include:

1. The patient's name, address, and date of birth;
2. The date the prescription order for a medication therapeutic plan is issued;
3. The clinical indication for medication therapy services;
4. The length of time for providing medication therapy services, if less than one (1) year; and
5. The authorizing physician's name and address;

(B) A prescription order for a medication therapeutic plan may be transmitted orally, electronically, or in writing. If an oral prescription order for a medication therapeutic plan is issued, all information required under subsection (2)(A) of this rule shall be documented by the pharmacist and maintained in the patient's record in accordance with section (7) of this rule;

(C) The pharmacist shall review relevant prescription records, patient profiles, patient medical records, or other medical information to determine the services to be rendered; and

(D) In lieu of compliance with 20 CSR 2220-2.018, prescription orders for medication therapy services shall comply with the provisions of this rule, provided the pharmacist shall maintain the prescription order in the patient record required by section (7) of this rule and shall document any change or alteration made to the prescription ordered based on contact with the

prescriber in the applicable patient record.

(3) Authorizing Physician Requirements.

(A) The authorizing physician shall be actively engaged in the practice of medicine in the state of Missouri and shall hold a current and unrestricted Missouri physician license pursuant to Chapter 334, RSMo.

(B) The authorizing physician shall be responsible for the oversight of the medication therapy services provided by the pharmacist that are authorized by protocol. The authorizing physician shall also consider the level of skill, education, training, and competence of the pharmacist and ensure that the activities authorized by the protocol are consistent with the pharmacist's level of skill, education, training, and competence.

(C) The written protocol shall be reviewed and signed by the pharmacist and the authorizing physician at least annually and revised as needed. The authorizing physician and pharmacist shall document the date of the annual review on the written protocol.

(D) The authorizing physician shall review the pharmacist's medication therapy service activities regularly, but not less than once every three (3) months. If the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, the review requirements shall be satisfied if the pharmacist's work and services are reviewed every three (3) months by a clinical care committee, pharmacy and therapeutics committee, or a reviewing body/committee of the health care entity that includes a Missouri-licensed physician. The review required by this subsection may be accomplished in person or by electronic means.

(E) The practice location of the authorizing physician shall be no further than fifty (50) miles by road from the pharmacist identified in the written protocol.

(F) An authorizing physician shall notify the Missouri State Board of Registration for the Healing Arts of a written protocol for medication therapy services entered with a pharmacist at each renewal of the authorizing physician's license.

(4) Protocol Requirements.

(A) The medication therapy services performed by a pharmacist pursuant to the protocol shall be within the authorizing physician's scope of practice and within the skill, education, training, and competence of both the authorizing physician and the pharmacist.

(B) The written protocol between the authorizing physician and pharmacist shall, at a minimum, include the following:

1. The identity and signatures of the authorizing physician and pharmacist;

2. The effective dates of the protocol;

3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug categories included in the written protocol and the type of medication therapy services allowed in each case;

4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting medication therapy services;

5. Procedures for documenting medication therapy decisions made by the pharmacist and a plan for communication, feedback, and reporting to the authorizing physician concerning specific decisions made;

6. A mechanism and procedure that allows the authorizing physician to override, rescind, modify, or otherwise amend the protocol. All modifications or amendments to the protocol shall be documented in writing, signed, and dated by all involved parties prior to the implementation of such modification or amendment. The protocol may be immediately rescinded by the authorizing physician or the pharmacist with or without cause, provided the rescission is documented in writing. If any conflict arises regarding the professional judgment of the pharmacist and physician with regard to the subject of the medication therapy services, the physician has ultimate authority;

7. A statement that the pharmacist shall not delegate the responsibility of medication therapy services to another person;

8. A description of any authority granted to the pharmacist to administer any drug or medication including the identification of any such drug, medication, or device;

9. A description of drug therapy related patient assessment procedures or testing that may be ordered or performed by the pharmacist, including any authority to order or perform routine or other laboratory testing;

10. Provisions for allowing the pharmacist to access the patient's medical records for purposes of providing medication therapy services;

11. A provision for providing the authorizing physician access to patient records for medication therapy services provided by the pharmacist for patients of the authorizing physician;

12. Provisions establishing a course of action the pharmacist is authorized to follow to address emergency situations, including, but not limited to, anaphylactic or other adverse medication reactions, adverse needle sticks, or other adverse events;

13. Criteria for timely communication from the authorizing physician to the pharmacist and from the pharmacist to the authorizing physician, not inconsistent with the provisions of this rule;

14. The notification requirements required by section (5) of this rule; and

15. The method for reviewing the pharmacist's medication therapy work or services by the authorizing physician, as required by subsection (3)(D) of this rule.

(C) The written protocol shall include a description of medication therapy services the pharmacist is authorized to render or provide. Such services may include:

1. Assessing patient specific data and issues;

2. Establishing medication therapeutic goals or medication related action plans for identified medical conditions and medication related concerns;

3. Assessing and addressing adverse reactions and adverse drug events;

4. Modifying and monitoring medication regimens;

5. Evaluating treatment progress;

6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;

7. Medication reconciliation;

8. Drug utilization review;

9. Formulating and documenting personal medication records;

10. Documenting clinical outcomes;

11. Interpreting, monitoring, and assessing patient test results;

12. Initiation of drug therapy, as authorized by protocol; and

13. Patient education and counseling.

(D) The protocol required by this section shall be signed and dated by the authorizing physician and the pharmacist. If the protocol includes multiple authorizing physicians or

participating pharmacists, a separate protocol shall not be required for each physician or pharmacist if all authorizing physicians and pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol.

(E) Any revisions, modifications, or amendments to the protocol must be in writing. The authorizing physician shall promptly notify the pharmacist of any such revision, modification, or amendment and shall maintain documentation of the notification, including the date such notification was made. The authorizing physician may delegate the notification requirements of this subsection to an authorized designee, provided the physician shall be ultimately responsible for compliance with the notification requirements.

(F) A pharmacist shall not be authorized to adjust, change, or modify any controlled substance prescribed for a patient, except as authorized by state or federal law.

(G) The protocol shall be maintained by the authorizing physician and the pharmacist for a minimum of eight (8) years after termination of the protocol. The protocol may be maintained electronically.

(H) A protocol shall automatically and immediately terminate if the pharmacist ceases to maintain an active Missouri pharmacist license, the authorizing physician is deceased, or if the authorizing physician fails to maintain an active, unrestricted Missouri physician license.

(I) Pharmacy Residents. If specifically authorized by the protocol, a pharmacy resident shall be authorized to perform medication therapy services under the written protocol of a Missouri pharmacist in lieu of an individual protocol, if –

1. The resident holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy;

2. The resident is enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists; and

3. The resident is providing medication therapy services under the supervision of a Missouri pharmacist certified by the Missouri State Board of Pharmacy to perform medication therapy services.

(J) The provisions of subsection (4)(I) shall only apply to medication therapy services provided by a pharmacist as part of his/her residency training.

(5) Notification Requirements. A pharmacist shall comply with the following notification requirements:

(A) Within twenty-four (24) hours after learning of an anaphylactic or other adverse medication reaction, adverse needle stick, or other adverse event experienced by a patient, the pharmacist shall notify the patient's authorizing physician or an authorized designee of the authorizing physician;

(B) The pharmacist shall notify the authorizing physician or an authorized designee of the authorizing physician in the written protocol of any modification of therapy, within twenty-four (24) hours, provided the protocol may include more stringent notification requirements;

(C) A pharmacist shall be deemed in compliance with the notification requirements of this rule if the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, as defined by this rule, and documentation of the notifications required by this section is recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law; and

(D) Notifications required by this section shall be in writing unless otherwise authorized by the authorizing physician.

(6) Modifying Drug Therapy.

(A) A pharmacist may be authorized by protocol to modify a patient's non-controlled substance medication therapy, subject to the following:

1. If the pharmacist modifies medication therapy and a medication or device is to be dispensed, the pharmacist shall create a prescription for the medication or device modified under the authorizing physician's name. Such prescription may be dispensed by a licensed pharmacy and shall be maintained in the prescription records of the dispensing pharmacy as provided by the rules of the Missouri State Board of Pharmacy; and

2. If the pharmacist modifies medication therapy or a device, the pharmacist shall document such modification according to section (7) of this rule. Pharmacists providing medication therapy services for patients of a health care entity shall be deemed in compliance with the provisions of this subsection if the modification is documented in a patient medical record that the health care entity is required to maintain under state or federal law.

(B) The pharmacist shall not modify any controlled substance prescription. A prescription from the authorizing physician shall be required to modify a controlled substance.

(C) For purposes of 20 CSR 2150-5.026 and 20 CSR 2150-5.028, modification of medication therapy shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product or generic substitutions made pursuant to section 338.056, RSMo.

(7) Record Keeping.

(A) A pharmacist shall document and maintain an adequate patient record of medication therapy services provided to each patient. The records may be maintained in electronic format provided the records are capable of being printed for review by the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy. An adequate and complete patient record shall include documentation of the following:

1. The identification of the patient, including, name, birthdate, address, and telephone number;

2. The date(s) of any patient visit or consultation, including the reason for any such visit/consultation;

3. Any pertinent assessments, observations, or findings;

4. Any diagnostic testing recommended or performed;

5. The name of any medication or device modified and the strength, dose, dosage schedule, dosage form, and route of administration of any medication modified or administered;

6. Referrals to the authorizing physician;

7. Referrals for emergency care;

8. Any contact with the authorizing physician concerning the patient's treatment or medication therapy services plan;

9. Any informed consent for procedures, medications, or devices; and

10. Any consultation with any other treatment provider for the patient and the results of such consultation.

(B) Pharmacist Record Retention. Except as otherwise provided herein, records required to be maintained by a pharmacist pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements

are established for record keeping under state or federal law. All records required to be maintained by the pharmacist by this rule shall be maintained by the pharmacist at an address that shall be identified in the written protocol.

(C) Physician Record Retention. Except as otherwise provided herein, records required to be maintained by the authorizing physician pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements are established for record keeping pursuant to state or federal law.

(8) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board's designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(9) Nothing in this rule shall be construed to permit medical diagnosis of any condition by a pharmacist or the independent issuing of a prescription by a pharmacist.

(10) A pharmacist shall not violate or practice in a manner inconsistent with the provisions of this rule or a written protocol. A pharmacist's failure to abide by the requirements of this rule or the provisions of a written protocol shall be subject to disciplinary action pursuant to the provisions of Chapter 338, RSMo.

(11) The requirements of this rule shall not apply to the administration of vaccines pursuant to protocol as governed by 20 CSR 2150-5.025 or the administration of medication by protocol as governed by 20 CSR 2220-6.040.

(12) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy 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 protocol agreement.

(13) The provisions of 20 CSR 2150-5.026 to 20 CSR 2150-5.028 and 20 CSR 2220-6.060 to 20 CSR 2220-6.080 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy, as established by Chapter 334, RSMo, and Chapter 338, RSMo.

AUTHORITY: section 334.125, RSMo 2000, and sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011. Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.*

**Original authority: 334.125, RSMo 1959, amended 1993, 1995; 338.010, RSMo 1939, amended 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

20 CSR 2150-5.029 Pharmacist Authority to Prescribe Pursuant to Section 338.665

PURPOSE: This rule establishes requirements for pharmacists prescribing as authorized by section 338.665, RSMo.

(1) Definitions.

(A) A nicotine replacement therapy product; as defined by section 338.665, RSMo.

(2) Training. Pharmacists prescribing must be competent to perform the services provided and shall maintain ongoing/continued competency.

(3) Pharmacist prescribing and patient care activities must be safely and properly performed.

(A) Pharmacists shall collect patient or medical history to allow the pharmacist to properly assess the patient and safely provide patient care. Prior to prescribing, the pharmacist shall use a screening procedure based on generally accepted clinical guidelines to identify appropriate patients for treatment. The pharmacist shall refer high-risk patients or patients with a contraindication to the patient's primary care provider or an appropriate healthcare provider, as deemed necessary or appropriate.

(B) In addition to this rule, pharmacists shall comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and record-keeping, including, but not limited to, 20 CSR 2220-2.018. Pharmacists may provide a prescription to the patient or transmit a prescription for that patient to a pharmacy for dispensing.

(4) Patient medical records. Prescribing pharmacists shall maintain an adequate and complete patient medical record for each patient that documents the care provided. Patient medical records must be individually retrievable.

(A) At a minimum, the required patient medical record must include:

1. The patient's name, birthdate, address and telephone number;
2. The date(s) the patient was seen;
3. The patient's primary care provider, if provided;
4. Documentation of the patient screening as required by section (3) of this rule;
5. Any pertinent medical or medication information/history;
6. The name and dosage of any medication prescribed;
7. Any recommended medication treatment plan(s) or follow-up consultation(s); and
8. Any healthcare provider referrals.

(B) Patient medical records must be securely and confidentially maintained in compliance with applicable state and federal law. At a minimum, patient medical records must be maintained for five (5) years from the date created. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the Board of Pharmacy or an authorized designee of the Board of Pharmacy. Records not maintained at a pharmacy must be produced within three (3) business days of a request from the Board of Pharmacy.

AUTHORITY: section 334.125, RSMo 2016, and sections 338.010 and 338.665, RSMo Supp. 2019. Original rule filed March 9, 2020, effective Oct. 30, 2020.*

**Original authority: 334.125, RSMo 1959, amended 1993, 1995, 2014; 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; and 338.665, RSMo 2019.*

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 Arrangement with Nurses

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 and implements the Utilization of Telehealth by Nurses as required by section 335.175, RSMo and APRN involvement in the "Improved Access to Treatment for Opioid Addictions Act" (IATOA) pursuant to sections 334.104 and 630.875, RSMo.

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 following shall apply in 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:

1. If the APRN is providing services pursuant to section 335.175, RSMo, no mileage limitation shall apply;

2. If the APRN is not providing services pursuant to section 335.175, RSMo, and is practicing the collaborating physician and collaborating APRN shall practice within seventy-five (75) miles by road of one another.

3. Pursuant to section 630.875, RSMo, an APRN collaborating with a physician who is waiver-certified for the use of buprenorphine, may participate in the "Improved Access to Treatment for Opioid Addictions Program" (IATOAP) in any area of the state and provide all services and functions of an APRN. A remote collaborating physician working with an on-site APRN shall be considered to be on-site for the purposes of IATOAP.

(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 six (6) full-time equivalent APRNs, full-time equivalent physician assistants, full-time equivalent assistant physicians, or any combination thereof. This limitation shall not apply to collaborative arrangements of hospital employees providing

inpatient care service in hospitals as defined in Chapter 197, RSMo, or population-based public health services as defined in this rule or to a certified registered nurse anesthetist providing anesthesia services under the supervision of an anesthesiologist or other physician, dentist, or podiatrist who is immediately available if needed as set out in section 334.104(7), RSMo.

(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, and competence and shall not be delegated to any other 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 any 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 Pharmacopeial 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 cosigned 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 Schedule II-hydrocodone and 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 Schedule II-hydrocodone and 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. When issuing the initial prescription for an opioid controlled substance in treating a patient for acute pain, the APRN shall comply with requirements set forth in section 195.080, RSMo. Schedule II-hydrocodone and Schedule III narcotic controlled substance prescriptions shall be limited to a one hundred twenty- (120-) hour supply without refill. An APRN may prescribe buprenorphine, a Schedule III controlled substance, for up to a thirty- (30-) day supply without refill for patients receiving medication-assisted treatment for substance abuse disorders under the direction of the collaborating physician as described in sections 334.104 and 630.875, RSMo;

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 is practical, but in no case more than two (2) weeks after the patient has been seen by the collaborating APRN or RN. If the APRN is providing services pursuant to section 335.175, RSMo, the collaborating physician, or other physician designated in the collaborative practice arrangement, may conduct the examination and evaluation required by this section via live, interactive video or in person. Telehealth providers shall obtain the patient's or the patient's guardian's consent before telehealth services are initiated and shall document the patient's or the patient's guardian's consent in the patient's file or chart. All telehealth activities must comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 and all other applicable state and federal laws and regulations.

(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. If the APRN is providing services pursuant to section 335.175, RSMo, the collaborating physician may be present in person or the collaboration may occur via telehealth in order to meet the requirements of this section. Telehealth providers shall obtain the patient's or the patient's guardian's consent before telehealth services are initiated and shall document the patient's or the patient's guardian's consent in the patient's file or chart. All telehealth activities must comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 and all other applicable state and federal laws and regulations.

(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.

AUTHORITY: sections 334.125 and 335.175, RSMo 2016, and sections 334.104.3 and 335.036, RSMo Supp. 2018. 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. Rescinded and readopted: Filed April 30, 2010, effective Nov. 30, 2010. Amended: Filed Nov. 14, 2014, effective June 30, 2015. Emergency amendment filed April 16, 2018, effective April 26, 2018, expired Feb. 5, 2019. Amended: Filed April 16, 2018, effective Oct. 30, 2018. Emergency amendment filed Feb. 22, 2019, effective March 4, 2019, expired Aug. 30, 2019. Amended: Filed Feb. 22, 2019, effective Aug. 30, 2019. ** Emergency amendment filed March 28, 2022, effective April 11, 2022, expired Oct. 7, 2022.*

**Original authority: 334.104.3, RSMo 1993 amended 2002, 2003, 2006, 2008, 2009, 2012, 2013, 2015, 2018; 334.125, RSMo 1959, amended 1993, 1995, 2014; 335.036, RSMo 1975, amended 1981, 1985, 1993, 1995, 1999, 2007, 2008, 2011, 2018; and 335.175, RSMo 2013, 2016.*

***Pursuant to Executive Order 21-09, 20 CSR 2150-5.100, subsection (2)(B) was suspended from March 26, 2020 through December 31, 2021 and subsections (2)(C) and (4)(E) was suspended from April 2, 2020 through December 31, 2021.*