RULES OF

Department of Commerce and Insurance

Division 2220—State Board of Pharmacy

Chapter 6—Pharmaceutical Care Standards

TITLE 20 – DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220 – State Board of Pharmacy
Chapter 6 – Pharmaceutical Care Standards

20 CSR 2220-6.025 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: sections 338.140, 338.210, and 338.730, RSMo Supp. 2022. Original rule filed Aug. 10, 2022, effective Feb. 28, 2023.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1957, amended 2001, 2011, 2020; and 338.730, RSMo 2021.*

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

(Rescinded November 30, 2019)

AUTHORITY: sections 338.095, RSMo Supp. 1993, 338.010, RSMo Supp. 1990, 338.140, RSMo Supp. 1989 and 338.280, RSMo 1986. This rule originally filed as 4 CSR 220-6.030. Original rule filed March 1, 1994, effective Sept. 30, 1994. Moved to 20 CSR 2220-6.030, effective Aug. 28, 2006. Rescinded: Filed May 13, 2019, effective Nov. 30, 2019.

20 CSR 2220-6.040 Administration by Medical Prescription Order

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

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices pursuant to a medical prescription order, including vaccines.

(2) Except as otherwise provided by law, a pharmacist may not delegate medication administration to another person, except to an intern pharmacist or qualified pharmacy technician who has met the qualifications under subsections (3)(B)–(E) and is working under the direct supervision of a pharmacist who has met the qualifications to administer drugs pursuant to a medical order.

(A) 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 medication 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.

(B) Proof of an intern's or qualified pharmacy technician's compliance with subsections (3)(B)–(E) must be maintained by both the supervising pharmacist and the intern pharmacist/qualified pharmacy technician for a minimum of two (2) years.

(3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the board. To file a Notification of Intent, a pharmacist must –

(A) Hold a current Missouri pharmacist license;

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

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

1. Administration techniques, including hands-on training in routes of administration;
2. Drug storage and handling;
3. Informed consent requirements;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal; and
6. Identifying and treating adverse reactions, including anaphylactic reactions and needle sticks;

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

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

(4) General Requirements.

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

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

1. Drug administration procedures;
2. Authorized routes of administration;
3. Drug storage;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal and disposal of used/contaminated supplies;
6. Identifying and handling acute adverse events or immunization reactions, including anaphylactic reactions; and
7. Recordkeeping and notification procedures and requirements.

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

(D) Patients must be asked to remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

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

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

(B) The name of the patient to receive the drug;

(C) The name of the drug and dose to be administered;

(D) The route of administration;

(E) The date of the original order; and

(F) The date or schedule, if any, of each subsequent administration.

(6) Record Keeping.

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

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The medication name and dose. For vaccines and biologics, the manufacturer, expiration date, and lot number must also be documented and recorded;
4. For vaccines, the name and address of the patient's primary health care provider, as identified by the patient or an indication that a primary health care provider was not provided;
5. The identity of the administering pharmacist, or if applicable, the administering intern pharmacist or qualified pharmacy technician and his/her supervising pharmacist; and
6. If applicable, the nature of an adverse reaction and who was notified.

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

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

(A) For vaccines, a pharmacist shall inform the patient that the administration of the vaccine will be entered into the ShowMeVax system, as administered by the Department of Health and Senior Services. The patient shall attest to the inclusion of such information in the system by signing a form provided by the pharmacist. Entry into ShowMeVax must occur within fourteen (14) days. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist must provide a written report within fourteen (14) days of administration of a vaccine to the patient's primary health care provider, if provided by the patient, containing –

1. The identity of the patient;
2. The identity of the vaccine or vaccines administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration;

(B) The prescriber is notified within twenty-four (24) hours after learning of an adverse event or reaction experienced by a patient following administration. Notification is mandatory and cannot be waived. Vaccine adverse events or reactions must also be reported to the Vaccine Adverse Event Reporting System (VAERS) or its successor, within thirty (30) days;

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

(D) Notifications required by this section may be made electronically or in writing or via a common electronic medication record that is accessible to and shared by both the physician

and pharmacist. Documentation of the required notifications, including the notification date, must be maintained as required by subsection (6)(B) or electronically retrievable at the request of the board or the board's authorized designee.

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

(9) A qualified pharmacy technician administering medication pursuant to this rule must be supervised by a Missouri-licensed pharmacist who is authorized to administer medication pursuant to this rule and who is physically present on-site when the medication is administered.

AUTHORITY: section 338.280, RSMo 2016, and sections 338.010.1 and 338.140, RSMo Supp. 2020. Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008. Amended: Filed Dec. 15, 2017, effective June 30, 2018. ** Emergency amendment filed Nov. 25, 2020, effective Dec. 11, 2020, expired June 8, 2021. Amended: Filed Nov. 25, 2020, effective May 30, 2021.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-07, 20 CSR 2220-6.040, section (8) was suspended from July 13, 2020 through August 5, 2021.*

20 CSR 2220-6.050 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 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;

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, the Board of Registration for the Healing Arts and/or their authorized representative. 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)(B) 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: sections 338.010, 338.140, 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. Amended: Filed Feb. 9, 2018, effective Sept.*

*30, 2018. ** 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: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020.

***Pursuant to Executive Order 21-09, 20 CSR 2220-6.050, subsections (7)(A) and (7)(B) was suspended from July 13, 2020 through December 31, 2021.*

20 CSR 2220-6.055 Non-Dispensing Activities

PURPOSE: This rule establishes procedures and requirements for the performance of non-dispensing activities outside of a pharmacy.

(1) Pursuant to section 338.220, RSMo, a pharmacist may perform the following non-dispensing activities outside of a licensed pharmacy:

(A) Patient counseling/education, as authorized by Missouri law, provided the pharmacist shall be obligated to comply with 20 CSR 2220-2.190, when applicable;

(B) Obtain patient history/information;

(C) Review patient records/medical histories;

(D) Patient assessment/evaluation, as authorized by Missouri law;

(E) Billing and insurance claim submissions/review;

(F) Drug utilization review;

(G) Assess health plan and medication eligibility/coverage;

(H) Pharmacy compliance audits/evaluations;

(I) Administer drugs, vaccines, or biologicals, as authorized by law and the rules of the board;

(J) Peer review/peer consultations;

(K) Review, select, and develop formularies or plan/practice guidelines;

(L) Review compliance with benefit guidelines;

(M) Manage inventory, including purchasing and ordering;

(N) Manage/review information systems;

(O) Patient medication review;

(P) Consultation with other health care professionals;

(Q) Patient referrals;

(R) Prescription order entry/review, provided that a pharmacist shall only be authorized to accept a prescription on the premises of a Missouri licensed pharmacy, as required by section 338.095.5, RSMo; and

(S) Medication therapy management, pursuant to and as authorized by Chapter 338, RSMo, and the rules of the board.

(2) Confidentiality. A pharmacist, pharmacy technician, or intern pharmacist performing non-dispensing activities pursuant to this rule shall comply with all applicable state and federal confidentiality laws and regulations. Sufficient storage and security for confidential documents and electronic data processing hardware must be provided by the pharmacy permit holder or the pharmacist. In addition, data processing systems must utilize sufficient security software to ensure confidentiality and prevent unauthorized access. Any breach in the security or confidentiality of the data processing systems or confidential documents shall be documented and reported to the board in writing within seven (7) days of the breach.

(3) Notwithstanding any other provision of this rule, a pharmacist shall not meet with patients in the pharmacist's residence or living quarters.

(4) A pharmacist, pharmacy technician, or intern pharmacist performing non-dispensing activities pursuant to this rule shall ensure compliance with Chapter 338, RSMo, and the rules of the board at all times. Nothing in this rule shall be construed to eliminate or otherwise exempt any pharmacist, pharmacy technician, intern pharmacist, or pharmacy permit holder from the record-keeping, confidentiality, or security requirements otherwise imposed by Chapter 338, RSMo, or the rules of the board. Violations of this section shall constitute grounds for discipline.

(5) This rule shall not be construed to authorize a pharmacist to conduct the unauthorized practice of medicine or to conduct any activity for which a license is required pursuant to Chapters 330, 331, 332, 334, or 337, RSMo.

(6) A pharmacy technician and intern pharmacist may be used to assist a pharmacist with non-dispensing activities outside of a pharmacy subject to the following:

(A) The pharmacy technician/intern pharmacist must be under the direct supervision of a Missouri licensed pharmacist as required by 20 CSR 2220-2.710. The supervising pharmacist must ensure pharmacy technician/intern pharmacist activities comply with state and federal law and must provide the personal assistance, direction, and approval required to verify and ensure delegated non-dispensing activities are safely and properly performed;

(B) The pharmacy technician or intern pharmacist must have completed employer approved training in the activities performed and have an initial and, if applicable, annual documented assessment of proficiency. Documentation of the completed training and proficiency assessment must be maintained in the pharmacy's records for a minimum of two (2) years and provided to the board or the board's designee upon request;

(C) A sufficient mechanism must be in place to allow real-time communication between a pharmacist and the technician/intern pharmacist when needed. A pharmacist must be available to respond to pharmacy technician/intern pharmacist questions at all times non-dispensing activities are being performed; and

(D) Adequate security and supervision must be maintained at all times to prevent unauthorized access to, and unauthorized storage/transfer of, confidential patient information or patient records.

(E) The provisions of this section (6) do not apply to technicians or intern pharmacists engaged in delivering filled prescriptions/medication orders on behalf of the pharmacy as authorized by 20 CSR 2220-2.013.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2019, and sections 338.035 and 338.220, RSMo 2016. Emergency rule filed Oct. 23, 2009, effective Nov. 2, 2009, expired April 30, 2010. Original rule filed Oct. 22, 2009, effective June 30, 2010. ** Amended: Filed Feb. 7, 2020, effective Aug. 30, 2020. Emergency amendment filed June 5, 2020, effective June 19, 2020, expired Sept. 1, 2020.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.035, RSMo 1990, amended 1993, 1995, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-6.055, section (6) was suspended from March 20, 2020 through December 31, 2021.*

20 CSR 2220-6.060 General Provisions

PURPOSE: This rule establishes definitions for 20 CSR 2220-6.060 to 20 CSR 2220-6.080 governing medication therapy services by pharmacists.

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(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 2220-6.080;

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

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

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

20 CSR 2220-6.070 Certificate of Medication Therapeutic Plan Authority

PURPOSE: This rule establishes procedures for obtaining a certificate of medication therapeutic plan authority, as authorized by section 338.010, RSMo.

(1) A pharmacist shall obtain a certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient's medication therapy or device usage. Pharmacists with a certificate of medication therapeutic authority shall enter into a written protocol with a Missouri-licensed physician that complies with the requirements of 20 CSR 2220-6.080, prior to performing medication therapy services.

(2) Applicants for certification shall hold an active Missouri pharmacist license. Applications shall be submitted on forms provided by the Missouri State Board of Pharmacy and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof the applicant –

(A) Holds a doctor of pharmacy (PharmD) degree earned from a school, accredited by the Accreditation Council for Pharmacy Education (ACPE); or

(B) Has successfully completed a post-graduate medication therapy certificate course or program accredited or granted by the APCE, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, or the American Pharmacists Association; or

(C) Holds a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators; or

(D) Has completed a post-graduate medication therapy certificate course that, at a minimum, included training in the following areas:

1. Assessing patient specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medication conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Improving patient care and outcomes through medication therapy services;
6. Evaluating treatment progress;
7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
8. Medication reconciliation;
9. Drug utilization review;
10. Applicable state or federal law;
11. Formulating and documenting personal medication records;
12. Documenting clinical outcomes;
13. Interpreting, monitoring, ordering, and assessing patient test results; and
14. Patient education and counseling.

(3) Certificate Renewal. A certificate of medication therapeutic plan authority shall be renewed biennially with the certificate holder's Missouri pharmacist license. For purposes of renewal, six (6) of the continuing education hours required for renewing the certificate holder's Missouri pharmacist license shall be earned in courses/programs related to medication therapy management. The continuing education required by this rule shall be governed by the rules of the Missouri State Board of Pharmacy governing pharmacist continuing education.

(4) The Missouri State Board of Pharmacy may discipline or terminate a pharmacist's certificate of medication therapeutic plan authority if the Missouri State Board of Pharmacy determines that the pharmacist has violated the terms of a protocol, the requirements of Chapter 338, RSMo, or rules of the board governing medication therapy services or any other state or federal drug law.

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

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

20 CSR 2220-6.080 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 2220-6.060, 20 CSR 2220-6.070, and 20 CSR 2220-6.080, 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 2220-6.050 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 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.

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

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

20 CSR 2220-6.100 Pharmacy Standards for Dispensing Blood-Clotting Products

PURPOSE: This rule implements the provisions of section 338.400, RSMo, and establishes pharmacy standards for dispensing blood-clotting products.

(1) Definitions. The following definitions are hereby adopted and applicable to this rule:

(A) "Bleeding disorder," a medical condition characterized by a deficiency or absence of one (1) or more essential blood-clotting components in the human blood, including all forms of hemophilia, acquired hemophilia, von Willebrand's disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood-clotting. As defined by section 338.400, RSMo, "bleeding disorder" does not include a bleeding condition secondary to another medical condition or diagnosis, except for acquired hemophilia;

(B) "Blood-clotting product," a medicine approved for distribution by the federal Food and Drug Administration (FDA) that is used for the treatment and prevention of symptoms associated with bleeding disorders, including, but not limited to, recombinant and plasma derived factor products, von Willebrand factor products, antifibrinolytics, bypass products for patients with inhibitors, prothrombin complex concentrates, and activated prothrombin complex concentrates. Except as otherwise provided by section 338.400, RSMo, a "blood-clotting product" does not include medical products approved solely for the treatment or prevention of side effects of a blood-clotting drug or medication;

(C) "Established patient," For purposes of section 338.400, RSMo, and this rule, an "established patient" shall be defined as a bleeding disorder patient that has been dispensed a legend blood-clotting product by the pharmacy on more than three (3) occassions in a single calendar year; and

(D) "Pharmacy," an entity engaged in the practice of pharmacy as defined in section 338.100, RSMo, that provides blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders.

(2) General Requirements. All Missouri licensed pharmacists and pharmacy permit holders shall comply with the following requirements when dispensing blood-clotting factor concentrates:

(A) Prescriptions for blood-clotting factor concentrates shall be dispensed as written or authorized by the prescribing physician, in accordance with state and federal law. No changes or substitutions shall be made unless approved by the prescriber. If the pharmacy has received prescriber authorization to change or substitute the blood-clotting factor concentrate originally prescribed, the patient or the patient's designee shall be notified and counseled regarding the change or substitution prior to dispensing via the preferred contact method identified by the patient or designee pursuant to subsection (2)(E);

(B) If requested by the patient or the patient's designee, the pharmacy shall ship and deliver blood-clotting factor concentrates to the patient or the patient's designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations. Nonemergency situations shall include, but may not be limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices must be used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements;

(C) Patients must be provided with a designated pharmacy contact telephone number for reporting problems with a delivery or product on each dispensing at no cost to the patient;

(D) Unless otherwise authorized by the patient or the patient's designee, the pharmacy shall contact the patient for authorization to dispense prior to shipping a refill of any blood-clotting product to the patient. The date of patient authorization shall be documented in the pharmacy's prescription records;

(E) Barring extenuating circumstances, prescriptions for blood clotting factor concentrates shall be dispensed within plus or minus ten percent (10%) of prescribed assays, or as otherwise authorized or directed by the prescriber; and

(F) Recalls or Withdrawals. Prior to dispensing any blood clotting factor concentrate, the pharmacy shall ask the patient or the patient's designee to designate a preferred contact method for receiving notifications in the event of a recall or withdrawal of the concentrate dispensed or any related ancillary infusion equipment and supplies dispensed by the pharmacy. The preferred contact method shall be documented with the patient information required by 20 CSR 2220-2.190(2).

1. Notice of concentrate or ancillary infusion equipment and supplies recalls and withdrawals shall be provided to the patient via the patient's preferred contact method within twenty-four (24) hours of receipt of a recall or withdrawal notification from the manufacturer or any state or federal entity that requires or recommends patient notification. The pharmacy shall also notify the prescribing physician within twenty-four (24) hours of such recall or withdrawal and shall obtain a prescription for an alternative product if a new or amended prescription is required to dispense or deemed necessary and appropriate by the prescriber.

2. If attempts to contact the patient via the preferred contact method are unsuccessful, the pharmacy shall mail notification to the patient or the patient's authorized designee within the required twenty-four (24) hours or the next business day.

3. The time, date, and method of notification to the patient and prescriber shall be documented in the pharmacy's records and maintained for two (2) years from the date of recall or withdrawal.

(3) In addition to the provisions of section (2), pharmacies that dispense blood-clotting products to established patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, shall comply with the following standards of care:

(A) The pharmacy shall annually notify the board in writing of the pharmacy's intent to provide legend blood-clotting products for bleeding disorder patients. Notification shall be made on or before January 31 of each calendar year in a manner and form approved by the board;

(B) The pharmacy shall identify in advance, or make arrangements with, a supplier or suppliers capable of providing all brands, assays, and vial sizes of blood-clotting products approved by the federal FDA, including products manufactured from human plasma and those manufactured from recombinant technology techniques. A list of all designated or identified suppliers shall be maintained at the pharmacy and

made available during inspection. This requirement shall not be construed to require a pharmacy to purchase products prior to receiving a valid prescription order;

(C) A pharmacist shall be available twenty-four (24) hours a day, seven (7) days a week, every day of the year, either on-site or on call, to fill prescriptions for blood-clotting products, within the time frames designated by section 338.400, RSMo, and the provisions of this rule;

(D) Pharmacists engaged in dispensing or filling blood-clotting factor concentrates or who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients shall have sufficient knowledge, experience, and training to perform the duties assigned. To ensure continued competency, pharmacists engaged in counseling bleeding disorder patients shall complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment or therapy, or blood-clotting disorders or diseases each biennial renewal period. The continuing education required by this rule may be used to satisfy the pharmacist's continuing education requirements. Proof of compliance with this section shall be maintained at the pharmacy for a minimum of four (4) calendar years and shall be made available during inspection or at the request of the board;

(E) If requested by the patient or the patient's designee, the pharmacy shall provide for the shipment and delivery of blood-clotting products to the patient or the patient's designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations;

(F) Established patients shall be provided access to blood-clotting products within twelve (12) hours of notification from a physician of the patient's emergent need for a blood-clotting product. For purposes of this section, determination of an emergent need shall be within the professional medical judgment of the physician. Emergent need requests shall be documented in the pharmacy's prescription records;

(G) The pharmacy shall provide or have available for purchase containers for the disposal of hazardous waste, including, but not limited to, sharp or equivalent biohazard waste containers;

(H) At a minimum, the pharmacy shall provide or have available for purchase ancillary equipment and supplies required to infuse a blood-clotting therapy product into a human vein, including, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs. If supplies are depleted, the pharmacy shall restock the required ancillary equipment and supplies in a reasonable amount of time which shall not exceed seven (7) calendar days;

(I) The pharmacy shall have contact information available for a nurse or nursing service or agency with experience in providing infusion related nursing services or nursing services for bleeding disorder patients if such services are not provided by the pharmacy;

(J) If requested by the patient or the patient's authorized designee, the pharmacist shall explain any known insurance copayments, deductibles, coinsurance payments, or lifetime maximum insurance payment limits. For purposes of complying with this section, the pharmacy may rely on information supplied by the patient's insurer; and

(K) The pharmacy shall register with the National Patient Notification System, or its successor, to receive recall notification for all products included in the National Patient Notification System. The pharmacy shall maintain current and accurate contact information with the National Patient Notification System.

(4) Pharmacies that provide legend blood-clotting products to treat or prevent symptoms of established bleeding disorder patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, shall develop and follow written policies and procedures to ensure compliance with section 338.400, RSMo, and the provisions of this rule. The pharmacy shall review the policies and procedures on an annual basis and document such review. At a minimum, the pharmacy's written policies and procedures must include procedures for:

(A) Processing prescriptions for blood-clotting products by pharmacy staff to ensure the timely handling and dispensing of blood-clotting products;

(B) Processing partial fill requests by patients to reduce or eliminate excessive dispensing;

(C) Providing and documenting recall notifications in accordance with this rule;

(D) Transferring, dispensing, refilling, or delivering blood-clotting factor concentrates to established patients in the event of an emergency or disaster;

(E) Notifying patients prior to terminating business or terminating the dispensing of any blood-clotting factor concentrate or prior to a known or an anticipated termination of pharmacy services for a bleeding disorder patient. Notification shall be provided in writing and, when reasonably possible, shall be provided a minimum of seven (7) days prior to any such termination;

(F) Shipping or providing blood-clotting products to the patient within the time frames required herein;

(G) Receiving, processing, and dispensing prescription or dispensing requests for a blood-clotting product to bleeding disorder patients, including procedures for handling and processing physician request indicating a patient's emergent need for a blood-clotting product;

(H) Ensuring appropriate cold chain management and packaging practices are used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements; and

(I) Handling and processing preauthorization notifications and requests and communicating preauthorization requirements to the patient and applicable prescriber.

(5) This rule shall not be construed to require dispensing without appropriate payment or payment arrangements. If the pharmacy is waiting for authorization, certification, or other action from a third-party payer prior to dispensing, the pharmacy shall notify the patient that the prescription is available for dispensing and explain any alternative payment options. Notification shall be provided as soon as reasonably practicable. At a minimum, however, notification shall be provided to the patient prior to the expiration of the shipping and delivery time frames required by subsection (2)(E), (3)(B), or (3)(F) of this rule.

AUTHORITY: section 338.280, RSMo 2000, and sections 338.140 and 338.400, RSMo Supp. 2012. Original rule filed Nov. 13, 2012, effective May 30, 2013.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.280, RSMo 1951, amended 1971, 1981; and 338.400, RSMo 2011.*

20 CSR 2220-6.200 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 or the board's authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

AUTHORITY: sections 338.010, 338.140, and 338.665, RSMo Supp. 2019. Original rule filed March 9, 2020, effective Oct. 30, 2020.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.665, RSMo 2019.*