PROPOSED RULE

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 his/her 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 record-keeping.

(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 health care 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 finger stick 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 on-going 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.

(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 health care 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 31st 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.

(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, section 210.115 and section 210.330, 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

(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.


PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the Missouri Register. No public hearing is scheduled.