SECOND REGULAR SESSION

# HOUSE BILL NO. 2304

## 100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE CHRISTOFANELLI.

3506H.04I DANA RADEMAN MILLER, Chief Clerk

## AN ACT

To repeal section 338.010, RSMo, and to enact in lieu thereof three new sections relating to HIV treatment.

*Be it enacted by the General Assembly of the state of Missouri, as follows:*

Section A. Section 338.010, RSMo, is repealed and three new sections enacted in lieu thereof, to be known as sections 338.010, 338.730, and 338.735, to read as follows:

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons at least seven years of age or the age recommended by the Centers for Disease Control and Prevention, whichever is higher, or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, meningitis, and viral influenza vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; the prescribing and dispensing of any nicotine replacement therapy

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

product under section 338.665; **the dispensing of HIV preexposure prophylaxis under section 338.730; the dispensing of HIV postexposure prophylaxis under section 338.735;** and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he or she is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a collaborative practice arrangement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall

be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

12. In addition to other requirements established by the joint promulgation of rules by the board of pharmacy and the state board of registration for the healing arts:

(1) A pharmacist shall administer vaccines by protocol in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);

(2) A pharmacist who is administering a vaccine shall request a patient to remain in the pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions. Such pharmacist shall have adopted emergency treatment protocols;

(3) In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon completion, and shall display the certification in his or her pharmacy where vaccines are delivered.

13. 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. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist shall provide a written report within fourteen 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.

**338.730. 1. Notwithstanding any other law to the contrary, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.**

**2. For purposes of this section, "preexposure prophylaxis" means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board of pharmacy to meet the same clinical eligibility recommendations provided in CDC guidelines.**

**3. For purposes of this section, "CDC guidelines" means the "2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update: A Clinical Practice Guideline" or any subsequent guidelines published by the federal Centers for Disease Control and Prevention.**

**4. Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board of pharmacy, in consultation with the board of healing arts, on the use of preexposure prophylaxis and postexposure prophylaxis. The board of pharmacy shall consult with the board of healing arts as well as relevant stakeholders including, but not limited to, the department of health and senior services, on training programs that are appropriate to meet the requirements of this subsection.**

**5. A pharmacist may furnish at least a thirty-day supply, and up to a sixty-day supply, of preexposure prophylaxis to a patient if all of the following conditions are met:**

**(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days 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 pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region;**

**(2) 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; and**

**(3) The patient does not report taking any contraindicated medications.**

**6. The pharmacist shall provide counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breast-feeding, 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 child-bearing capacity.**

**7. A pharmacist shall notify the patient that the patient shall be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist shall not furnish a sixty-day supply of preexposure prophylaxis to a single patient more than once every two years.**

**8. A pharmacist shall document, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.**

**9. A pharmacist shall not furnish, under the provisions of this section, more than a sixty-day supply of preexposure prophylaxis to a single patient more than once every two years. A pharmacist may furnish more than a sixty-day supply of preexposure prophylaxis to a single patient if directed by a prescriber.**

**10. A pharmacist shall notify the patient's primary care provider that the pharmacist completed the requirements specified in this section. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.**

**11. A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the patient to whom the drug is furnished to waive the consultation required by the board of pharmacy.**

**12. The director of the division of professional registration may promulgate all necessary rules and regulations for the administration of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2020, shall be invalid and void.**

**338.735. 1. Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.**

**2. For purposes of this section, "postexposure prophylaxis" means any of the following:**

**(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily;**

**(2) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily; or**

**(3) Another drug or drug combination determined by the board of pharmacy to meet the same clinical eligibility recommendations provided in CDC guidelines.**

**3. For purposes of this section, "CDC guidelines" means the "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United States, 2016" or any subsequent guidelines published by the federal Centers for Disease Control and Prevention.**

**4. Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board of pharmacy, in consultation with the board of healing arts, on the use of preexposure prophylaxis and postexposure prophylaxis. The board of pharmacy shall consult with the board of healing arts as well as relevant stakeholders including, but not limited to, the department of health and senior services, on training programs that are appropriate to meet the requirements of this subdivision.**

**5. A pharmacist may furnish a complete course of postexposure prophylaxis if all of the following conditions are met:**

**(1) A pharmacist screens the patient and determines the exposure occurred within the previous seventy-two hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines;**

**(2) A pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Section 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines;**

**(3) A pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include 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 and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV; and**

**(4) A pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.**

**6. A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the patient to whom the drug is furnished to waive the consultation required by the board of pharmacy.**

**7. The director of the division of professional registration may promulgate all necessary rules and regulations for the administration of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2020, shall be invalid and void.**

✓