By Senator Osgood

32-01179-23 2023416__

A bill to be entitled

An act relating to antiretroviral drugs; creating s. 465.1861, F.S.; defining terms; authorizing pharmacists to order and dispense HIV preexposure and postexposure prophylaxis drugs without a prescription under certain circumstances; requiring pharmacists to complete specified training before ordering or dispensing such drugs without a prescription; authorizing pharmacists to order and dispense a specified supply of preexposure prophylaxis or a full course of postexposure prophylaxis, as applicable, to patients without a prescription if certain conditions are met; authorizing the Board of Pharmacy, in consultation with the Board of Medicine, the Department of Health, and other relevant stakeholders, to adopt rules; creating s. 627.4291, F.S.; defining terms; prohibiting certain health insurers from requiring prior authorization or step-therapy protocols for certain antiretroviral drugs; providing an exception; prohibiting health insurers from refusing to cover, or allowing pharmacy benefit managers to refuse to cover, preexposure or postexposure prophylaxis drugs for a specified reason; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 465.1861, Florida Statutes, is created to read:

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

465.1861 Antiretroviral drugs.—

(1) As used in this section, the term:

(a) "HIV" means the human immunodeficiency virus.

(b) "Postexposure prophylaxis" means any of the following:

1. A fixed-dose combination of 300 milligrams of tenofovir disoproxil fumarate with 200 milligrams of emtricitabine, taken once daily, in combination with either 400 milligrams of raltegravir, taken twice daily, or 50 milligrams of dolutegravir, taken once daily.

2. A fixed-dose combination of 300 milligrams of tenofovir disoproxil fumarate with 200 milligrams of emtricitabine, taken once daily, in combination with a fixed-dose combination of 800 milligrams of darunavir and 100 milligrams of ritonavir, taken once daily.

3. Any other drug or drug combination deemed by the board to meet the same clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV.

(c) "Preexposure prophylaxis" means a fixed-dose combination of 300 milligrams of tenofovir disoproxil fumarate with 200 milligrams of emtricitabine, or another drug or combination of drugs which the board deems to meet the clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for preexposure prophylaxis for the prevention of HIV infection.

(2) Notwithstanding any other law, a pharmacist may order or dispense an HIV preexposure or postexposure prophylaxis

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

without a prescription in accordance with this section. Before ordering or dispensing such medicinal drug, a pharmacist must first complete a training program approved by the board which includes all of the following:

(a) Training in the use of preexposure and postexposure prophylaxis.

(b) Information about any financial assistance programs for preexposure and postexposure prophylaxis.

(c) Any other topic the board deems appropriate. The board shall consult with the Board of Medicine, the department, and other relevant stakeholders when making such determinations.

(3) A pharmacist may order or dispense up to two 30-day supplies of preexposure prophylaxis to a patient without a prescription if all of the following conditions are met:

(a) The patient is HIV negative, as documented by a negative HIV test result obtained within the preceding 7 days from an HIV antigen or antibody test, an antibody-only test, or a rapid, point-of-care fingerstick blood test approved by the United States Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist must order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist must verify the test results to his or her satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test must direct the patient to a primary care provider and provide to the patient a list of available providers and clinics in the region.

(b) The patient does not report any signs or symptoms of acute HIV infection, as indicated on a self-reported checklist

of acute HIV infection signs and symptoms provided by the pharmacist.

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

(d) The pharmacist has not ordered two 30-day supplies of preexposure prophylaxis for the patient without a prescription in the preceding 2-year period.

(e) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, consistent with guidelines issued by the United States Centers for Disease Control and Prevention, to include, at a minimum, 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. A pharmacist may not allow a patient to waive this counseling.

(f) The pharmacist informs the patient that he or she must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may order only up to two 30-day supplies without a prescription in one 2-year period for each patient.

(g) The pharmacist documents and maintains in the pharmacy records system a record of each 30-day supply of preexposure prophylaxis ordered or dispensed to the patient without a prescription. The pharmacist or pharmacy must maintain such records for at least 4 years.

(h) The pharmacist notifies the patient's primary care provider that the pharmacist ordered or dispensed preexposure

prophylaxis to the patient in accordance with 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 must provide the patient a list of physicians, surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.

(4) A pharmacist may order or dispense a full course of postexposure prophylaxis to a patient without a prescription if all of the following conditions are met:

(a) The pharmacist screens the patient and determines that the exposure occurred within the previous 72 hours, and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with the applicable guidelines issued by the United States Centers for Disease Control and Prevention.

(b) The pharmacist provides to the patient HIV testing that is deemed a waived test under the federal Clinical Laboratory Improvement Amendments of 1988 or the patient is willing to undergo HIV testing in accordance with s. 381.004. However, if the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may order or dispense postexposure prophylaxis to the patient.

(c) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis, consistent with guidelines issued by the United States Centers for Disease Control and Prevention, to include, at a minimum, 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

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

diseases. The pharmacist must also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV. A pharmacist may not allow a patient to waive this counseling.

(d) The pharmacist notifies the patient's primary care provider that the pharmacist ordered or dispensed the postexposure prophylaxis in accordance with 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 must provide the patient a list of physicians, surgeons, clinics, or other health care service providers to contact regarding follow-up care for postexposure prophylaxis.

(5) The board, in consultation with the Board of Medicine, the department, and other relevant stakeholders, may adopt rules to implement this section.

Section 2. Section 627.4291, Florida Statutes, is created to read:

627.4291 Coverage of antiretroviral drugs.—

(1) As used in this section, the term:

(a) "AIDS" means acquired immune deficiency syndrome.

(b) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603; a managed care plan as defined in s. 409.962; or a health maintenance organization as defined in s. 641.19(12).

(c) "HIV" means the human immunodeficiency virus.

(d) "Insured" means a person who is covered under a policy delivered or issued for delivery in this state by a health insurer.

(e) "Prior authorization" means a process by which an

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

insured does not receive coverage for a particular prescription drug until the insured's health care provider submits to the insured's health insurer a request for approval and the health insurer determines that the prescription drug is covered by the insured's policy.

(f) "Step-therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs determined as medically appropriate for an insured for a specified medical condition are covered by a policy.

(2) Notwithstanding any other law, a health insurer providing major medical or similar comprehensive coverage or benefits to residents in this state on or after July 1, 2023, may not require prior authorization or a step-therapy protocol under the policy for a covered antiretroviral drug that is medically necessary for the prevention of HIV or AIDS, including, but not limited to, preexposure and postexposure prophylaxis, except as provided in subsection (3).

(3) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of HIV or AIDS, a health insurer is not required to cover all of the therapeutically equivalent versions without prior authorization or step-therapy protocols if at least one therapeutically equivalent version is covered without prior authorization or a step-therapy protocol.

(4) A health insurer may not refuse to cover, or allow a pharmacy benefit manager to refuse to cover, preexposure or postexposure prophylaxis solely on the basis that it was ordered or dispensed by a licensed pharmacist in accordance with s. 465.1861.

Section 3. This act shall take effect July 1, 2023.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.