

By Senator Rodrigues

27-00961A-21

2021928__

1 A bill to be entitled
2 An act relating to antiretroviral drugs; creating s.
3 465.1861, F.S.; defining terms; authorizing
4 pharmacists to order and dispense preexposure and
5 postexposure prophylaxis drugs without a prescription
6 under certain circumstances; requiring pharmacists to
7 complete specified training before ordering or
8 dispensing such drugs without a prescription;
9 authorizing pharmacists to order and dispense a
10 specified supply or full course, as applicable, of
11 such drugs to patients without prescriptions if
12 certain conditions are met; authorizing the Board of
13 Pharmacy, in consultation with the Board of Medicine,
14 the Department of Health, and other relevant
15 stakeholders, to adopt rules; creating s. 627.4291,
16 F.S.; defining terms; prohibiting certain health
17 insurers from requiring prior authorization or step-
18 therapy protocols for certain antiretroviral drugs;
19 providing an exception; prohibiting health insurers
20 from refusing to cover, or allowing pharmacy benefit
21 managers to refuse to cover, preexposure or
22 postexposure prophylaxis drugs under certain
23 circumstances; providing an effective date.

24
25 Be It Enacted by the Legislature of the State of Florida:

26
27 Section 1. Section 465.1861, Florida Statutes, is created
28 to read:

29 465.1861 Antiretroviral drugs.-

27-00961A-21

2021928__

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

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

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

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

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

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

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

56 (2) Notwithstanding any other law, a pharmacist may order
57 or dispense an HIV preexposure or postexposure prophylaxis
58 without a prescription in accordance with this section. Before

27-00961A-21

2021928__

59 ordering or dispensing such medicinal drug, a pharmacist must
60 first complete a training program approved by the board which
61 includes all of the following:

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

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

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

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

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

85 (b) The patient does not report any signs or symptoms of
86 acute HIV infection, as indicated on a self-reported checklist
87 of acute HIV infection signs and symptoms which was provided by

27-00961A-21

2021928__

88 the pharmacist.

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

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

94 (e) The pharmacist provides counseling to the patient on
95 the ongoing use of preexposure prophylaxis, to include, at a
96 minimum, education about side effects, safety during pregnancy
97 and breastfeeding, adherence to recommended dosing, and the
98 importance of timely testing and treatment, as applicable, for
99 HIV, renal function, hepatitis B, hepatitis C, sexually
100 transmitted diseases, and pregnancy for individuals of child-
101 bearing capacity. A pharmacist may not allow a patient to waive
102 this counseling.

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

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

113 (h) The pharmacist notifies the patient's primary care
114 provider that the pharmacist ordered or dispensed preexposure
115 prophylaxis to the patient in accordance with this section. If
116 the patient does not have a primary care provider or refuses

27-00961A-21

2021928__

117 consent to notify the patient's primary care provider, the
118 pharmacist must provide the patient a list of physicians,
119 surgeons, clinics, or other health care service providers to
120 contact regarding ongoing care for preexposure prophylaxis.

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

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

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

136 (c) The pharmacist provides counseling to the patient on
137 the use of postexposure prophylaxis, consistent with guidelines
138 issued by the United States Centers for Disease Control and
139 Prevention, to include, at a minimum, education about side
140 effects, safety during pregnancy and breastfeeding, adherence to
141 recommended dosing, and the importance of timely testing and
142 treatment, as applicable, for HIV and sexually transmitted
143 diseases. The pharmacist must also inform the patient of the
144 availability of preexposure prophylaxis for persons who are at
145 substantial risk of acquiring HIV. A pharmacist may not allow a

27-00961A-21

2021928__

146 patient to waive this counseling.

147 (d) The pharmacist notifies the patient's primary care
148 provider that the pharmacist ordered or dispensed the
149 postexposure prophylaxis in accordance with this section. If the
150 patient does not have a primary care provider or refuses consent
151 to notify the patient's primary care provider, the pharmacist
152 must provide the patient a list of physicians, surgeons,
153 clinics, or other health care service providers to contact
154 regarding followup care for postexposure prophylaxis.

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

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

160 627.4291 Coverage of antiretroviral drugs.-

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

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

163 (b) "Health insurer" means an authorized insurer offering
164 health insurance as defined in s. 624.603, a managed care plan
165 as defined in s. 409.962(10), or a health maintenance
166 organization as defined in s. 641.19(12).

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

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

171 (e) "Prior authorization" means a process by which an
172 insured does not receive coverage for a particular prescription
173 drug until the insured's health care provider submits to the
174 insured's health insurer a request for approval and the health

27-00961A-21

2021928__

175 insurer determines that the prescription drug is covered by the
176 insured's policy.

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

181 (2) Notwithstanding any other law, a health insurer
182 providing major medical or similar comprehensive coverage or
183 benefits to residents in this state on or after July 1, 2021,
184 may not require prior authorization or a step-therapy protocol
185 under the policy for a covered antiretroviral drug that is
186 medically necessary for the prevention of HIV or AIDS,
187 including, but not limited to, preexposure and postexposure
188 prophylaxis, except as provided in subsection (3).

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

196 (4) A health insurer may not refuse to cover, or allow a
197 pharmacy benefit manager to refuse to cover, preexposure or
198 postexposure prophylaxis solely on the basis that it was ordered
199 or dispensed by a licensed pharmacist in accordance with s.
200 465.1861.

201 Section 3. This act shall take effect July 1, 2021.