

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 prophylaxes to patients without
6 prescriptions under certain circumstances; requiring
7 pharmacists to complete specified training before
8 ordering or dispensing such prophylaxes to patients
9 without prescriptions; authorizing pharmacists to
10 order and dispense specified supplies of preexposure
11 prophylaxes and full courses of postexposure
12 prophylaxes to patients without prescriptions if
13 certain conditions are met; authorizing the Board of
14 Pharmacy, in consultation with the Board of Medicine,
15 the Department of Health, and other relevant
16 stakeholders, to adopt rules; creating s. 627.4291,
17 F.S.; defining terms; prohibiting certain health
18 insurers from requiring prior authorizations or step-
19 therapy protocols for certain antiretroviral drugs;
20 providing an exception; prohibiting health insurers
21 from refusing to cover, or allowing pharmacy benefit
22 managers to refuse to cover, preexposure and
23 postexposure prophylaxes under certain circumstances;
24 providing an effective date.
25

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

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

30 | 465.1861 Antiretroviral drugs.-

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

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

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

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

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

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

50 | (c) "Preexposure prophylaxis" means a fixed-dose

51 combination of 300 milligrams of tenofovir disoproxil fumarate
52 with 200 milligrams of emtricitabine, or another drug or
53 combination of drugs which the board deems to meet the clinical
54 eligibility recommendations of the United States Centers for
55 Disease Control and Prevention guidelines for preexposure
56 prophylaxis for the prevention of HIV infection.

57 (2) Notwithstanding any other law, a pharmacist may order
58 or dispense an HIV preexposure or postexposure prophylaxis to a
59 patient without a prescription in accordance with this section.
60 Before ordering or dispensing such medicinal drug, a pharmacist
61 must first complete a training program approved by the board
62 which includes all of the following:

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

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

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

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

73 (a) The patient is HIV negative, as documented by a
74 negative HIV test result, obtained within the preceding 7 days,
75 from an HIV antigen or antibody test, an antibody-only test, or

76 a rapid, point-of-care fingerstick blood test approved by the
77 federal Food and Drug Administration. If the patient does not
78 provide evidence of a negative HIV test in accordance with this
79 paragraph, the pharmacist must order an HIV test. If the test
80 results are not transmitted directly to the pharmacist, the
81 pharmacist must verify the test results to his or her
82 satisfaction. If the patient tests positive for HIV infection,
83 the pharmacist or person administering the test must direct the
84 patient to a primary care provider and provide to the patient a
85 list of available providers and clinics in the region.

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

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

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

95 (e) The pharmacist provides counseling to the patient on
96 the ongoing use of preexposure prophylaxis, consistent with
97 guidelines issued by the United States Centers for Disease
98 Control and Prevention, including, but not limited to, education
99 about side effects, safety during pregnancy and breastfeeding,
100 adherence to recommended dosing, and the importance of timely

101 testing and treatment, as applicable, for HIV, renal function,
102 hepatitis B, hepatitis C, sexually transmitted diseases, and
103 pregnancy for individuals of child-bearing capacity. A
104 pharmacist may not allow a patient to waive this counseling.

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

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

116 (h) The pharmacist notifies the patient's primary care
117 provider that the pharmacist ordered or dispensed preexposure
118 prophylaxis to the patient in accordance with this section. If
119 the patient does not have a primary care provider or refuses to
120 consent to such notification, the pharmacist must provide the
121 patient a list of physicians, surgeons, clinics, or other health
122 care providers to contact regarding ongoing care for preexposure
123 prophylaxis.

124 (4) A pharmacist may order or dispense a full course of
125 postexposure prophylaxis to a patient without a prescription if

126 all of the following conditions are met:

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

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

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

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151 patient to waive this counseling.

152 (d) The pharmacist notifies the patient's primary care
153 provider that the pharmacist ordered or dispensed the
154 postexposure prophylaxis in accordance with this section. If the
155 patient does not have a primary care provider or refuses to
156 consent to such notification, the pharmacist must provide the
157 patient a list of physicians, surgeons, clinics, or other health
158 care providers to contact regarding followup care for
159 postexposure prophylaxis.

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

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

165 627.4291 Coverage of antiretroviral drugs.-

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

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

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

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

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

176 (e) "Prior authorization" means a process by which an
177 insured does not receive coverage for a particular prescription
178 drug until the insured's health care provider submits to the
179 insured's health insurer a request for approval and the health
180 insurer determines that the prescription drug is covered by the
181 insured's policy.

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

186 (2) Notwithstanding any other law, a health insurer
187 providing major medical or similar comprehensive coverage or
188 benefits to residents in this state on or after July 1, 2022,
189 may not require prior authorization or a step-therapy protocol
190 under the policy for a covered antiretroviral drug that is
191 medically necessary for the prevention of HIV or AIDS,
192 including, but not limited to, preexposure and postexposure
193 prophylaxis, except as provided in subsection (3).

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

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201 (4) A health insurer may not refuse to cover, or allow a
202 pharmacy benefit manager to refuse to cover, preexposure or
203 postexposure prophylaxis solely on the basis that it was ordered
204 or dispensed by a licensed pharmacist in accordance with s.
205 465.1861.

206 Section 3. This act shall take effect July 1, 2022.