

By Senator Cruz

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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 HIV 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 of preexposure prophylaxis or a full
11 course of postexposure prophylaxis, as applicable, to
12 patients without prescriptions if certain conditions
13 are met; authorizing the Board of Pharmacy, in
14 consultation with the Board of Medicine, the
15 Department of Health, and other relevant stakeholders,
16 to adopt rules; creating s. 627.4291, F.S.; defining
17 terms; prohibiting certain health insurers from
18 requiring prior authorization or step-therapy
19 protocols for certain antiretroviral drugs; providing
20 an exception; prohibiting health insurers from
21 refusing to cover, or allowing pharmacy benefit
22 managers to refuse to cover, preexposure or
23 postexposure prophylaxis drugs under certain
24 circumstances; providing an effective date.

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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:

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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

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59 without a prescription in accordance with this section. Before
60 ordering or dispensing such medicinal drug, a pharmacist must
61 first complete a training program approved by the board which
62 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 for
66 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 United States Food and Drug Administration. If the patient does
78 not provide evidence of a negative HIV test in accordance with
79 this paragraph, the pharmacist must order an HIV test. If the
80 test 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

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88 of acute HIV infection signs and symptoms provided by the
89 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, to include, at a
97 minimum, education about side effects, safety during pregnancy
98 and breastfeeding, adherence to recommended dosing, and the
99 importance of timely testing and treatment, as applicable, for
100 HIV, renal function, hepatitis B, hepatitis C, sexually
101 transmitted diseases, and pregnancy for individuals of child-
102 bearing capacity. A pharmacist may not allow a patient to waive
103 this counseling.

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

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

114 (h) The pharmacist notifies the patient's primary care
115 provider that the pharmacist ordered or dispensed preexposure
116 prophylaxis to the patient in accordance with this section. If

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117 the patient does not have a primary care provider or refuses
118 consent to notify the patient's primary care provider, the
119 pharmacist must provide the patient a list of physicians,
120 surgeons, clinics, or other health care service providers to
121 contact regarding ongoing care for preexposure prophylaxis.

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

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

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

137 (c) The pharmacist provides counseling to the patient on
138 the use of postexposure prophylaxis, consistent with guidelines
139 issued by the United States Centers for Disease Control and
140 Prevention, to include, at a minimum, education about side
141 effects, safety during pregnancy and breastfeeding, adherence to
142 recommended dosing, and the importance of timely testing and
143 treatment, as applicable, for HIV and sexually transmitted
144 diseases. The pharmacist must also inform the patient of the
145 availability of preexposure prophylaxis for persons who are at

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146 substantial risk of acquiring HIV. A pharmacist may not allow a
147 patient to waive this counseling.

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

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

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

161 627.4291 Coverage of antiretroviral drugs.-

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

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

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

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

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

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

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175 insured's health insurer a request for approval and the health
176 insurer determines that the prescription drug is covered by the
177 insured's policy.

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

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

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

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

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