

HB 607

2021

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; providing rulemaking
13 authority; creating s. 627.4291, F.S.; defining terms;
14 prohibiting certain health insurers from requiring
15 prior authorization or step-therapy protocols for
16 certain antiretroviral drugs; providing an exception;
17 prohibiting health insurers from refusing to cover, or
18 allowing pharmacy benefit managers to refuse to cover,
19 preexposure or postexposure prophylaxis drugs under
20 certain circumstances; providing an effective date.

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

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

26 465.1861 Antiretroviral drugs.-

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

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

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

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

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

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

46 (c) "Preexposure prophylaxis" means a fixed-dose
47 combination of 300 milligrams of tenofovir disoproxil fumarate
48 with 200 milligrams of emtricitabine, or another drug or
49 combination of drugs which the board deems to meet the clinical
50 eligibility recommendations of the United States Centers for

51 Disease Control and Prevention guidelines for preexposure
52 prophylaxis for the prevention of HIV infection.

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

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

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

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

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

69 (a) The patient is HIV negative, as documented by a
70 negative HIV test result, obtained within the preceding 7 days,
71 from an HIV antigen or antibody test, an antibody-only test, or
72 a rapid, point-of-care fingerstick blood test approved by the
73 federal Food and Drug Administration. If the patient does not
74 provide evidence of a negative HIV test in accordance with this
75 paragraph, the pharmacist must order an HIV test. If the test

76 results are not transmitted directly to the pharmacist, the
77 pharmacist must verify the test results to his or her
78 satisfaction. If the patient tests positive for HIV infection,
79 the pharmacist or person administering the test must direct the
80 patient to a primary care provider and provide to the patient a
81 list of available providers and clinics in the region.

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

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

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

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

100 (f) The pharmacist informs the patient that the patient

101 must be seen by a primary care provider to receive subsequent
102 prescriptions for preexposure prophylaxis and that a pharmacist
103 may order only up to two 30-day supplies without a prescription
104 in one 2-year period for each patient.

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

110 (h) The pharmacist notifies the patient's primary care
111 provider that the pharmacist ordered or dispensed preexposure
112 prophylaxis to the patient in accordance with this section. If
113 the patient does not have a primary care provider or refuses
114 consent to notify the patient's primary care provider, the
115 pharmacist must provide the patient a list of physicians,
116 surgeons, clinics, or other health care providers to contact
117 regarding ongoing care for preexposure prophylaxis.

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

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

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

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

145 (d) The pharmacist notifies the patient's primary care
146 provider that the pharmacist ordered or dispensed the
147 postexposure prophylaxis in accordance with this section. If the
148 patient does not have a primary care provider or refuses consent
149 to notify the patient's primary care provider, the pharmacist
150 must provide the patient a list of physicians, surgeons,

151 clinics, or other health care providers to contact regarding
152 followup care for postexposure prophylaxis.

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

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

158 627.4291 Coverage of antiretroviral drugs.-

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

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

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

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

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

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

175 (f) "Step-therapy protocol" means a protocol or program

176 that establishes the specific sequence in which prescription
177 drugs determined as medically appropriate for an insured for a
178 specified medical condition are covered by a policy.

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

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

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

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