

By Senator Hooper

16-01471-21

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1                                   A bill to be entitled  
2       An act relating to step-therapy protocols; amending s.  
3       627.42393, F.S.; revising the circumstances under  
4       which step-therapy protocols may not be required;  
5       providing definitions; requiring health insurers to  
6       publish on their websites and provide to their  
7       insureds specified information; requiring health  
8       insurers to grant or deny protocol exemption requests  
9       and respond to appeals within specified timeframes;  
10      providing requirements for granting and denying  
11      protocol exemption requests; authorizing health  
12      insurers to request specified documentation under  
13      certain circumstances; providing construction;  
14      amending s. 641.31, F.S.; revising the circumstances  
15      under which step-therapy protocols may not be  
16      required; providing definitions; requiring health  
17      maintenance organizations to publish on their websites  
18      and provide to their subscribers specified  
19      information; requiring health maintenance  
20      organizations to grant or deny protocol exemption  
21      requests and respond to appeals within specified  
22      timeframes; providing requirements for granting and  
23      denying protocol exemption requests; authorizing  
24      health maintenance organizations to request specified  
25      documentation under certain circumstances; providing  
26      construction; providing an effective date.

27  
28   Be It Enacted by the Legislature of the State of Florida:  
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30 Section 1. Section 627.42393, Florida Statutes, is amended  
31 to read:

32 627.42393 Step-therapy protocol restrictions and  
33 exemptions.—

34 (2)-(1) STEP-THERAPY PROTOCOL RESTRICTIONS.—In addition to  
35 the protocol exemptions granted under subsection (3), a health  
36 insurer issuing a major medical individual or group policy may  
37 not require a step-therapy protocol under the policy for a  
38 covered prescription drug requested by an insured if:

39 (a) The insured has previously been approved to receive the  
40 prescription drug through the completion of a step-therapy  
41 protocol required by a separate health coverage plan; and

42 (b) The insured provides documentation originating from the  
43 health coverage plan that approved the prescription drug as  
44 described in paragraph (a) indicating that the health coverage  
45 plan paid for the drug on the insured's behalf during the 90  
46 days immediately before the request.

47 (1)-(2) DEFINITIONS.—As used in this section, the term:

48 (a) "Health coverage plan" means any of the following which  
49 is currently or was previously providing major medical or  
50 similar comprehensive coverage or benefits to the insured:

51 1.-(a) A health insurer or health maintenance organization.

52 2.-(b) A plan established or maintained by an individual  
53 employer as provided by the Employee Retirement Income Security  
54 Act of 1974, Pub. L. No. 93-406.

55 3.-(c) A multiple-employer welfare arrangement as defined in  
56 s. 624.437.

57 4.-(d) A governmental entity providing a plan of self-  
58 insurance.

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59 (b) "Health insurer" has the same meaning as in s.  
60 627.42392(1).

61 (c) "Preceding prescription drug or medical treatment"  
62 means a prescription drug, medical procedure, or course of  
63 treatment that must be used pursuant to a health insurer's step-  
64 therapy protocol as a condition of coverage under a health  
65 insurance policy to treat an insured's condition.

66 (d) "Protocol exemption" means a determination by a health  
67 insurer that a step-therapy protocol is not medically  
68 appropriate or indicated for the treatment of an insured's  
69 condition, and the health insurer authorizes the use of another  
70 prescription drug, medical procedure, or course of treatment  
71 prescribed or recommended by the treating health care provider  
72 for the insured's condition.

73 (e) "Step-therapy protocol" means a written protocol that  
74 specifies the order in which certain prescription drugs, medical  
75 procedures, or courses of treatment must be used to treat an  
76 insured's condition.

77 (f) "Urgent care situation" means an injury or condition of  
78 an insured which, if medical care and treatment are not provided  
79 earlier than the time the medical profession generally considers  
80 reasonable for a nonurgent situation, would, in the opinion of  
81 the insured's treating physician, physician assistant, or  
82 advanced practice registered nurse:

83 1. Seriously jeopardize the insured's life, health, or  
84 ability to regain maximum function; or

85 2. Subject the insured to severe pain that cannot be  
86 adequately managed.

87 (3) STEP-THERAPY PROTOCOL EXEMPTIONS; REQUIREMENTS AND

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88 PROCEDURES.—

89 (a) A health insurer shall publish on its website and  
90 provide to an insured in writing a procedure for the insured and  
91 his or her health care provider to request a protocol exemption.  
92 The procedure must include:

93 1. The manner in which an insured or health care provider  
94 may request a protocol exemption. The health insurer must have  
95 available a prior authorization form for the insured or health  
96 care provider to complete and submit for a protocol exemption  
97 request.

98 2. The manner and timeframe in which the health insurer is  
99 required to authorize or deny a protocol exemption request or to  
100 respond to an appeal of the health insurer's granting or denial  
101 of a request.

102 3. The conditions under which the protocol exemption  
103 request must be granted.

104 (b)1. A health insurer must authorize or deny a protocol  
105 exemption request or respond to an appeal of the health  
106 insurer's granting or denial of a request within:

107 a. Seventy-two hours after receiving a completed prior  
108 authorization form for nonurgent care situations.

109 b. Twenty-four hours after receiving a completed prior  
110 authorization form for urgent care situations.

111 2. A granting of the request must specify the approved  
112 prescription drug, medical procedure, or course of treatment  
113 benefits.

114 3. A denial of the request must include a detailed written  
115 explanation of the reason for the denial, the clinical rationale  
116 that supports the denial, and the procedure for appealing the

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117 health insurer's determination.

118 (c) A health insurer must grant a protocol exemption  
119 request if any of the following applies:

120 1. A preceding prescription drug or medical treatment is  
121 contraindicated or will likely cause an adverse reaction or  
122 physical or mental harm to the insured.

123 2. A preceding prescription drug or medical treatment is  
124 expected to be ineffective based on the insured's medical  
125 history and the clinical evidence of the characteristics of the  
126 preceding prescription drug or medical treatment.

127 3. The insured has previously received a prescription drug,  
128 medical procedure, or course of treatment that is in the same  
129 pharmacologic class or has the same mechanism of action as the  
130 preceding prescription drug or medical treatment, and such  
131 prescription drug, medical procedure, or course of treatment  
132 lacked efficacy or effectiveness or adversely affected the  
133 insured.

134 4. A preceding prescription drug or medical treatment is  
135 not in the insured's best interest because his or her use of the  
136 preceding prescription drug or medical treatment is expected to:

137 a. Cause a significant barrier to the insured's adherence  
138 to or compliance with his or her plan of care;

139 b. Worsen the insured's medical condition that exists  
140 simultaneously with, but independently of, the condition under  
141 treatment; or

142 c. Decrease the insured's ability to achieve or maintain  
143 his or her ability to perform daily activities.

144 5. A preceding prescription drug or medical treatment is an  
145 opioid prescription drug and the protocol exemption request is

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146 for a nonopioid prescription drug or treatment with a likelihood  
 147 of similar or better results.

148 (d) A health insurer may request a copy of relevant  
 149 documentation from an insured's medical record in support of a  
 150 protocol exemption request.

151 (4)~~(3)~~ CONSTRUCTION.—This section:

152 (a) Does not require a health insurer to add a drug to its  
 153 prescription drug formulary or to cover a prescription drug that  
 154 the insurer does not otherwise cover.

155 (b) May not be construed to:

156 1. Alter any other law with regard to provisions limiting  
 157 coverage for drugs that are not approved by the United States  
 158 Food and Drug Administration.

159 2. Require coverage for any drug if the United States Food  
 160 and Drug Administration has determined that the use of the drug  
 161 is contraindicated.

162 3. Require coverage for a drug that is not otherwise  
 163 approved for any indication by the United States Food and Drug  
 164 Administration.

165 4. Affect the determination as to whether particular  
 166 levels, dosages, or usage of a medication associated with bone  
 167 marrow transplant procedures are covered under an individual or  
 168 group health insurance policy or health maintenance contract.

169 5. Apply to specified disease or supplemental policies.

170 Section 2. Subsection (46) of section 641.31, Florida  
 171 Statutes, is reordered and amended to read:

172 641.31 Health maintenance contracts.—

173 (46) (b)~~(a)~~ Step-therapy protocol restrictions.—In addition  
 174 to the protocol exemptions granted under paragraph (c), a health

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175 maintenance organization issuing major medical coverage through  
 176 an individual or group contract may not require a step-therapy  
 177 protocol under the contract for a covered prescription drug  
 178 requested by a subscriber if:

179 1. The subscriber has previously been approved to receive  
 180 the prescription drug through the completion of a step-therapy  
 181 protocol required by a separate health coverage plan; and

182 2. The subscriber provides documentation originating from  
 183 the health coverage plan that approved the prescription drug as  
 184 described in subparagraph 1. indicating that the health coverage  
 185 plan paid for the drug on the subscriber's behalf during the 90  
 186 days immediately before the request.

187 ~~(a) (b)~~ Definitions.—As used in this subsection, the term:

188 1. "Health coverage plan" means any of the following which  
 189 previously provided or is currently providing major medical or  
 190 similar comprehensive coverage or benefits to the subscriber:

191 ~~a.1.~~ A health insurer or health maintenance organization.~~†~~

192 ~~b.2.~~ A plan established or maintained by an individual  
 193 employer as provided by the Employee Retirement Income Security  
 194 Act of 1974, Pub. L. No. 93-406.~~†~~

195 ~~c.3.~~ A multiple-employer welfare arrangement as defined in  
 196 s. 624.437.~~†~~~~or~~

197 ~~d.4.~~ A governmental entity providing a plan of self-  
 198 insurance.

199 2. "Preceding prescription drug or medical treatment" means  
 200 a prescription drug, medical procedure, or course of treatment  
 201 that must be used pursuant to a health maintenance  
 202 organization's step-therapy protocol as a condition of coverage  
 203 under a health maintenance contract to treat a subscriber's

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204 condition.

205 3. "Protocol exemption" means a determination by a health  
206 maintenance organization that a step-therapy protocol is not  
207 medically appropriate or indicated for the treatment of a  
208 subscriber's condition, and the health maintenance organization  
209 authorizes the use of another prescription drug, medical  
210 procedure, or course of treatment prescribed or recommended by  
211 the treating health care provider for the subscriber's  
212 condition.

213 4. "Step-therapy protocol" means a written protocol that  
214 specifies the order in which certain prescription drugs, medical  
215 procedures, or courses of treatment must be used to treat a  
216 subscriber's condition.

217 5. "Urgent care situation" means an injury or condition of  
218 a subscriber which, if medical care and treatment are not  
219 provided earlier than the time the medical profession generally  
220 considers reasonable for a nonurgent situation, would, in the  
221 opinion of the subscriber's treating physician, physician  
222 assistant, or advanced practice registered nurse:

223 a. Seriously jeopardize the subscriber's life, health, or  
224 ability to regain maximum function; or

225 b. Subject the subscriber to severe pain that cannot be  
226 adequately managed.

227 (c) Step-therapy protocol exemptions; requirements and  
228 procedures.-

229 1. A health maintenance organization shall publish on its  
230 website and provide to a subscriber in writing a procedure for  
231 the subscriber and his or her health care provider to request a  
232 protocol exemption. The procedure must include:

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233 a. The manner in which a subscriber or health care provider  
234 may request a protocol exemption. A health maintenance  
235 organization must have available a prior authorization form for  
236 the subscriber or health care provider to complete and submit  
237 for a protocol exemption request.

238 b. The manner and timeframe in which the health maintenance  
239 organization is required to authorize or deny a protocol  
240 exemption request or to respond to an appeal of the health  
241 maintenance organization's granting or denial of a request.

242 c. The conditions under which the protocol exemption  
243 request must be granted.

244 2.a. A health maintenance organization must authorize or  
245 deny a protocol exemption request or respond to an appeal of the  
246 health maintenance organization's granting or denial of a  
247 request within:

248 (I) Seventy-two hours after receiving a completed prior  
249 authorization form for nonurgent care situations.

250 (II) Twenty-four hours after receiving a completed prior  
251 authorization form for urgent care situations.

252 b. A granting of the request must specify the approved  
253 prescription drug, medical procedure, or course of treatment  
254 benefits.

255 c. A denial of the request must include a detailed written  
256 explanation of the reason for the denial, the clinical rationale  
257 that supports the denial, and the procedure for appealing the  
258 health maintenance organization's determination.

259 3. A health maintenance organization must grant a protocol  
260 exemption request if any of the following applies:

261 a. A preceding prescription drug or medical treatment is

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262 contraindicated or will likely cause an adverse reaction or  
263 physical or mental harm to the subscriber.

264 b. A preceding prescription drug or medical treatment is  
265 expected to be ineffective based on the subscriber's medical  
266 history and the clinical evidence of the characteristics of the  
267 preceding prescription drug or medical treatment.

268 c. The subscriber has previously received a prescription  
269 drug, medical procedure, or course of treatment that is in the  
270 same pharmacologic class or has the same mechanism of action as  
271 the preceding prescription drug or medical treatment, and such  
272 prescription drug, medical procedure, or course of treatment  
273 lacked efficacy or effectiveness or adversely affected the  
274 subscriber.

275 d. A preceding prescription drug or medical treatment is  
276 not in the subscriber's best interest because his or her use of  
277 the preceding prescription drug or medical treatment is expected  
278 to:

279 (I) Cause a significant barrier to the subscriber's  
280 adherence to or compliance with his or her plan of care;

281 (II) Worsen the subscriber's medical condition that exists  
282 simultaneously with, but independently of, the condition under  
283 treatment; or

284 (III) Decrease the subscriber's ability to achieve or  
285 maintain his or her ability to perform daily activities.

286 e. A preceding prescription drug or medical treatment is an  
287 opioid prescription drug and the protocol exemption request is  
288 for a nonopioid prescription drug or treatment with a likelihood  
289 of similar or better results.

290 4. A health maintenance organization may request a copy of

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291 relevant documentation from a subscriber's medical record in  
292 support of a protocol exemption request.

293 (d)(e) Construction.—This subsection:

294 1. Does not require a health maintenance organization to  
295 add a drug to its prescription drug formulary or to cover a  
296 prescription drug that the health maintenance organization does  
297 not otherwise cover.

298 2. May not be construed to:

299 a. Alter any other law with regard to provisions limiting  
300 coverage for drugs that are not approved by the United States  
301 Food and Drug Administration.

302 b. Require coverage for any drug if the United States Food  
303 and Drug Administration has determined that the use of the drug  
304 is contraindicated.

305 c. Require coverage for a drug that is not otherwise  
306 approved for any indication by the United States Food and Drug  
307 Administration.

308 d. Affect the determination as to whether particular  
309 levels, dosages, or usage of a medication associated with bone  
310 marrow transplant procedures are covered under a health  
311 maintenance contract.

312 e. Apply to specified disease or supplemental contracts.

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