

By Senator Hooper

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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) ~~(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.