

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 limiting the types of health insurers that may not
6 require step-therapy protocol under certain
7 circumstances; providing definitions; requiring health
8 insurers to publish on their websites and provide to
9 their insureds specified information; requiring health
10 insurers to grant or deny protocol exemption requests
11 and respond to appeals within specified timeframes;
12 providing requirements for granting and denying
13 protocol exemption requests; authorizing health
14 insurers to request specified documentation under
15 certain circumstances; providing construction;
16 amending s. 641.31, F.S.; revising the circumstances
17 under which step-therapy protocols may not be
18 required; providing definitions; requiring health
19 maintenance organizations to publish on their websites
20 and provide to their subscribers specified
21 information; requiring health maintenance
22 organizations to grant or deny protocol exemption
23 requests and respond to appeals within specified
24 timeframes; providing requirements for granting and
25 denying protocol exemption requests; authorizing

26 health maintenance organizations to request specified
 27 documentation under certain circumstances; providing
 28 construction; providing an effective date.

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

32 Section 1. Section 627.42393, Florida Statutes, is amended
 33 to read:

34 627.42393 Step-therapy protocol restrictions and
 35 exemptions.—

36 (1)~~(2)~~ DEFINITIONS.—As used in this section, the term:

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

40 1.~~(a)~~ A health insurer or health maintenance organization.

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

44 3.~~(c)~~ A multiple-employer welfare arrangement as defined
 45 in s. 624.437.

46 4.~~(d)~~ A governmental entity providing a plan of self-
 47 insurance.

48 (b) "Health insurer" has the same meaning as in s.

49 627.42392(1) .

50 (c) "Preceding prescription drug or medical treatment"

51 means a prescription drug, medical procedure, or course of
52 treatment that must be used pursuant to a health insurer's step-
53 therapy protocol as a condition of coverage under a health
54 insurance policy to treat an insured's condition.

55 (d) "Protocol exemption" means a determination by a health
56 insurer that a step-therapy protocol is not medically
57 appropriate or indicated for the treatment of an insured's
58 condition, and the health insurer authorizes the use of another
59 prescription drug, medical procedure, or course of treatment
60 prescribed or recommended by the treating health care provider
61 for the insured's condition.

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

66 (f) "Urgent care situation" means an injury or condition
67 of an insured which, if medical care and treatment are not
68 provided earlier than the time the medical profession generally
69 considers reasonable for a nonurgent situation, would, in the
70 opinion of the insured's treating physician, physician
71 assistant, or advanced practice registered nurse:

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

74 2. Subject the insured to severe pain that cannot be
75 adequately managed.

76 (2) ~~(1)~~ STEP-THERAPY PROTOCOL RESTRICTIONS.—In addition to
 77 the protocol exemptions granted under subsection (3), a health
 78 insurer issuing a major medical individual or group policy may
 79 not require a step-therapy protocol under the policy for a
 80 covered prescription drug requested by an insured if:

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

84 (b) The insured provides documentation originating from
 85 the health coverage plan that approved the prescription drug as
 86 described in paragraph (a) indicating that the health coverage
 87 plan paid for the drug on the insured's behalf during the 90
 88 days immediately before the request.

89 (3) STEP-THERAPY PROTOCOL EXEMPTIONS; REQUIREMENTS AND
 90 PROCEDURES.—

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

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

100 2. The manner and timeframe in which the health insurer is

101 required to authorize or deny a protocol exemption request or to
102 respond to an appeal of the health insurer's granting or denial
103 of a request.

104 3. The conditions under which the protocol exemption
105 request must be granted.

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

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

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

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

116 3. A denial of the request must include a detailed written
117 explanation of the reason for the denial, the clinical rationale
118 that supports the denial, and the procedure for appealing the
119 health insurer's determination.

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

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

125 2. A preceding prescription drug or medical treatment is

126 expected to be ineffective based on the insured's medical
127 history and the clinical evidence of the characteristics of the
128 preceding prescription drug or medical treatment.

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

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

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

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

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

146 5. A preceding prescription drug or medical treatment is
147 an opioid prescription drug and the protocol exemption request
148 is for a nonopioid prescription drug or treatment with a
149 likelihood of similar or better results.

150 (d) A health insurer may request a copy of relevant

151 documentation from an insured's medical record in support of a
152 protocol exemption request.

153 (4)-(3) CONSTRUCTION.—This section:

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

157 (b) May not be construed to:

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

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

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

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

171 5. Apply to specified disease or supplemental policies.

172 Section 2. Subsection (46) of section 641.31, Florida
173 Statutes, is amended to read:

174 641.31 Health maintenance contracts.—

175 (46) (a)-(b) Definitions.—As used in this subsection, the

176 term:

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

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

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

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

186 ~~d.4.~~ A governmental entity providing a plan of self-
187 insurance.

188 2. "Preceding prescription drug or medical treatment"
189 means a prescription drug, medical procedure, or course of
190 treatment that must be used pursuant to a health maintenance
191 organization's step-therapy protocol as a condition of coverage
192 under a health maintenance contract to treat a subscriber's
193 condition.

194 3. "Protocol exemption" means a determination by a health
195 maintenance organization that a step-therapy protocol is not
196 medically appropriate or indicated for the treatment of a
197 subscriber's condition, and the health maintenance organization
198 authorizes the use of another prescription drug, medical
199 procedure, or course of treatment prescribed or recommended by
200 the treating health care provider for the subscriber's

201 condition.

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

206 5. "Urgent care situation" means an injury or condition of
207 a subscriber which, if medical care and treatment are not
208 provided earlier than the time the medical profession generally
209 considers reasonable for a nonurgent situation, would, in the
210 opinion of the subscriber's treating physician, physician
211 assistant, or advanced practice registered nurse:

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

214 b. Subject the subscriber to severe pain that cannot be
215 adequately managed.

216 (b) (46) (a) Step-therapy protocol restrictions.—In addition
217 to the protocol exemptions granted under paragraph (c), a health
218 maintenance organization issuing major medical coverage through
219 an individual or group contract may not require a step-therapy
220 protocol under the contract for a covered prescription drug
221 requested by a subscriber if:

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

225 2. The subscriber provides documentation originating from

226 the health coverage plan that approved the prescription drug as
227 described in subparagraph 1. indicating that the health coverage
228 plan paid for the drug on the subscriber's behalf during the 90
229 days immediately before the request.

230 (c) Step-therapy protocol exemptions; requirements and
231 procedures.-

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

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

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

246 c. The conditions under which the protocol exemption
247 request must be granted.

248 2.a. A health maintenance organization must authorize or
249 deny a protocol exemption request or respond to an appeal of the
250 health maintenance organization's granting or denial of a

251 request within:

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

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

256 b. A granting of the request must specify the approved
257 prescription drug, medical procedure, or course of treatment
258 benefits.

259 c. A denial of the request must include a detailed written
260 explanation of the reason for the denial, the clinical rationale
261 that supports the denial, and the procedure for appealing the
262 health maintenance organization's determination.

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

265 a. A preceding prescription drug or medical treatment is
266 contraindicated or will likely cause an adverse reaction or
267 physical or mental harm to the subscriber.

268 b. A preceding prescription drug or medical treatment is
269 expected to be ineffective based on the subscriber's medical
270 history and the clinical evidence of the characteristics of the
271 preceding prescription drug or medical treatment.

272 c. The subscriber has previously received a prescription
273 drug, medical procedure, or course of treatment that is in the
274 same pharmacologic class or has the same mechanism of action as
275 the preceding prescription drug or medical treatment, and such

276 prescription drug, medical procedure, or course of treatment
 277 lacked efficacy or effectiveness or adversely affected the
 278 subscriber.

279 d. A preceding prescription drug or medical treatment is
 280 not in the subscriber's best interest because his or her use of
 281 the preceding prescription drug or medical treatment is expected
 282 to:

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

285 (II) Worsen the subscriber's medical condition that exists
 286 simultaneously with, but independently of, the condition under
 287 treatment; or

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

290 e. A preceding prescription drug or medical treatment is
 291 an opioid prescription drug and the protocol exemption request
 292 is for a nonopioid prescription drug or treatment with a
 293 likelihood of similar or better results.

294 4. A health maintenance organization may request a copy of
 295 relevant documentation from a subscriber's medical record in
 296 support of a protocol exemption request.

297 (d) ~~(e)~~ Construction.—This subsection:

298 1. Does not require a health maintenance organization to
 299 add a drug to its prescription drug formulary or to cover a
 300 prescription drug that the health maintenance organization does

301 not otherwise cover.

302 2. May not be construed to:

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

306 b. Require coverage for any drug if the United States Food
 307 and Drug Administration has determined that the use of the drug
 308 is contraindicated.

309 c. Require coverage for a drug that is not otherwise
 310 approved for any indication by the United States Food and Drug
 311 Administration.

312 d. Affect the determination as to whether particular
 313 levels, dosages, or usage of a medication associated with bone
 314 marrow transplant procedures are covered under a health
 315 maintenance contract.

316 e. Apply to specified disease or supplemental contracts.

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