

By Senator Harrell

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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 defining terms; requiring health insurers to publish
6 on their websites and provide to their insureds
7 specified information; providing requirements for
8 procedures for requests and appeals of denials of
9 protocol exemptions; providing requirements for
10 authorizations and denials of protocol exemption
11 requests; authorizing health insurers to request
12 specified documentation under certain circumstances;
13 amending s. 641.31, F.S.; revising the circumstances
14 under which step-therapy protocols may not be
15 required; defining terms; requiring health maintenance
16 organizations to publish on their websites and provide
17 to their subscribers specified information; providing
18 requirements for procedures for requests and appeals
19 of denials of protocol exemptions; providing
20 requirements for authorizations and denials of
21 protocol exemption requests; authorizing health
22 maintenance organizations to request specified
23 documentation under certain circumstances; providing
24 an effective date.

25
26 Be It Enacted by the Legislature of the State of Florida:

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28 Section 1. Section 627.42393, Florida Statutes, is amended
29 to read:

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30 627.42393 Step-therapy protocol.-

31 (2)~~(1)~~ In addition to the protocol exemptions granted
32 pursuant to subsection (3), a health insurer issuing a major
33 medical individual or group policy may not require a step-
34 therapy protocol under the policy for a covered prescription
35 drug requested by an insured if:

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

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

44 (1)~~(2)~~ As used in this section, the term:

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

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

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

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

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

56 (b) "Protocol exemption" means a determination by a health
57 insurer to authorize the use of another prescription drug,
58 medical procedure, or course of treatment prescribed or

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59 recommended by the treating health care provider for the
60 insured's condition rather than the one specified by the health
61 insurer's step-therapy protocol.

62 (c) "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 (3)(a) A health insurer shall publish on its website and
67 provide to an insured in writing a procedure for the insured and
68 his or her health care provider to request a protocol exemption
69 or an appeal of the health insurer's denial of a protocol
70 exemption request. The procedure must include, at a minimum:

71 1. The manner in which the insured or health care provider
72 may request a protocol exemption, including a form to request
73 the protocol exemption.

74 2. The manner and timeframe in which the health insurer
75 must authorize or deny a protocol exemption request, including
76 the requirement that such response must occur within a
77 reasonable time.

78 3. The manner and timeframe in which the insured or health
79 care provider may appeal the health insurer's denial of a
80 protocol exemption request.

81 (b) An authorization of a protocol exemption request must
82 specify the approved prescription drug, medical procedure, or
83 course of treatment. A denial of a protocol exemption request
84 must include a written explanation of the reason for the denial,
85 the clinical rationale that supports the denial, and the
86 procedure for appealing the health insurer's denial.

87 (c) A health insurer may request relevant medical records

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88 in support of a protocol exemption request.

89 ~~(4)(3)~~ This section does not require a health insurer to
90 add a drug to its prescription drug formulary or to cover a
91 prescription drug that the insurer does not otherwise cover.

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

94 641.31 Health maintenance contracts.-

95 ~~(46)(b)~~ ~~(46)(a)~~ In addition to the protocol exemptions
96 granted under paragraph (c), a health maintenance organization
97 issuing major medical coverage through an individual or group
98 contract may not require a step-therapy protocol under the
99 contract for a covered prescription drug requested by a
100 subscriber if:

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

104 2. The subscriber provides documentation originating from
105 the health coverage plan that approved the prescription drug as
106 described in subparagraph 1. indicating that the health coverage
107 plan paid for the drug on the subscriber's behalf during the 90
108 days immediately before the request.

109 ~~(a)(b)~~ As used in this subsection, the term:

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

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

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

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117 c.3. A multiple-employer welfare arrangement as defined in
118 s. 624.437. ~~or~~

119 d.4. A governmental entity providing a plan of self-
120 insurance.

121 2. "Protocol exemption" means a determination by a health
122 maintenance organization to authorize the use of another
123 prescription drug, medical procedure, or course of treatment
124 prescribed or recommended by the treating health care provider
125 for the subscriber's condition rather than the one specified by
126 the health maintenance organization's step-therapy protocol.

127 3. "Step-therapy protocol" means a written protocol that
128 specifies the order in which certain prescription drugs, medical
129 procedures, or courses of treatment must be used to treat a
130 subscriber's condition.

131 (c)1. A health maintenance organization shall publish on
132 its website and provide to a subscriber in writing a procedure
133 for the subscriber and his or her health care provider to
134 request a protocol exemption or an appeal of the health
135 maintenance organization's denial of a protocol exemption
136 request. The procedure must include, at a minimum:

137 a. The manner in which the subscriber or health care
138 provider may request a protocol exemption, including a form to
139 request the protocol exemption.

140 b. The manner and timeframe in which the health maintenance
141 organization must authorize or deny a protocol exemption
142 request, including the requirement that such response must occur
143 within a reasonable time.

144 c. The manner and timeframe in which the subscriber or
145 health care provider may appeal the health maintenance

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146 organization's denial of a protocol exemption request.

147 2. An authorization of a protocol exemption request must
148 specify the approved prescription drug, medical procedure, or
149 course of treatment. A denial of a protocol exemption request
150 must include a written explanation of the reason for the denial,
151 the clinical rationale that supports the denial, and the
152 procedure for appealing the health maintenance organization's
153 denial.

154 3. A health maintenance organization may request relevant
155 medical records in support of a protocol exemption request.

156 (d)~~(e)~~ This subsection does not require a health
157 maintenance organization to add a drug to its prescription drug
158 formulary or to cover a prescription drug that the health
159 maintenance organization does not otherwise cover.

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