ENROLLED **HB459**

2022 Legislature

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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.
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Page 1 of 7

2022 Legislature

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:			
30	627.42393 Step-therapy protocol			
31	(1) (2) As used in this section, the term:			
32	(a) "Health coverage plan" means any of the following			
33	which is currently or was previously providing major medical or			
34	similar comprehensive coverage or benefits to the insured:			
35	1.(a) A health insurer or health maintenance organization.			
36	2.(b) A plan established or maintained by an individual			
37	employer as provided by the Employee Retirement Income Security			
38	Act of 1974, Pub. L. No. 93-406.			
39	3.(c) A multiple-employer welfare arrangement as defined			
40	in s. 624.437.			
41	<u>4.(d)</u> A governmental entity providing a plan of self-			
42	insurance.			
43	(b) "Protocol exemption" means a determination by a health			
44	insurer to authorize the use of another prescription drug,			
45	medical procedure, or course of treatment prescribed or			
46	recommended by the treating health care provider for the			
47	insured's condition rather than the one specified by the health			
48	insurer's step-therapy protocol.			
49	(c) "Step-therapy protocol" means a written protocol that			
50	specifies the order in which certain prescription drugs, medical			
	Page 2 of 7			

2022 Legislature

51	procedures, or courses of treatment must be used to treat an
52	insured's condition.
53	(2) (1) In addition to the protocol exemptions granted
54	under subsection (3), a health insurer issuing a major medical
55	individual or group policy may not require a step-therapy
56	protocol under the policy for a covered prescription drug
57	requested by an insured if:
58	(a) The insured has previously been approved to receive
59	the prescription drug through the completion of a step-therapy
60	protocol required by a separate health coverage plan; and
61	(b) The insured provides documentation originating from
62	the health coverage plan that approved the prescription drug as
63	described in paragraph (a) indicating that the health coverage
64	plan paid for the drug on the insured's behalf during the 90
65	days immediately before the request.
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	authorizes or denies a protocol exemption request, which must
	Page 3 of 7

2022 Legislature

76	occur within a reasonable time.
77	3. The manner and timeframe in which the insured or health
78	care provider may appeal the health insurer's denial of a
79	protocol exemption request.
80	(b) An authorization of a protocol exemption request must
81	specify the approved prescription drug, medical procedure, or
82	course of treatment. A denial of a protocol exemption request
83	must include a written explanation of the reason for the denial,
84	the clinical rationale that supports the denial, and the
85	procedure for appealing the health insurer's denial.
86	(c) A health insurer may request relevant medical records
87	in support of a protocol exemption request.
88	(4)(3) This section does not require a health insurer to
89	add a drug to its prescription drug formulary or to cover a
90	prescription drug that the insurer does not otherwise cover.
91	Section 2. Subsection (46) of section 641.31, Florida
92	Statutes, is amended to read:
93	641.31 Health maintenance contracts
94	(46) <u>(a)</u> As used in this subsection, the term:
95	1. "Health coverage plan" means any of the following which
96	previously provided or is currently providing major medical or
97	similar comprehensive coverage or benefits to the subscriber:
98	<u>a.</u> 1. A health insurer or health maintenance organization <u>.</u> ;
99	b.2. A plan established or maintained by an individual
100	employer as provided by the Employee Retirement Income Security
	Page 4 of 7

FLORIDA HOUSE OF REPRESENTATIVES

ENROLLED

2022 Legislature

101 Act of 1974, Pub. L. No. 93-406.;

102 <u>c.3.</u> A multiple-employer welfare arrangement as defined in 103 s. 624.437.; or

104 <u>d.4.</u> A governmental entity providing a plan of self-105 insurance.

106 <u>2. "Protocol exemption" means a determination by a health</u> 107 <u>maintenance organization to authorize the use of another</u> 108 <u>prescription drug, medical procedure, or course of treatment</u> 109 <u>prescribed or recommended by the treating health care provider</u> 110 <u>for the subscriber's condition rather than the one specified by</u> 111 <u>the health maintenance organization's step-therapy protocol.</u>

112 <u>3. "Step-therapy protocol" means a written protocol that</u> 113 <u>specifies the order in which certain prescription drugs, medical</u> 114 <u>procedures, or courses of treatment must be used to treat a</u> 115 subscriber's condition.

116 <u>(b) (a)</u> In addition to the protocol exemptions granted 117 <u>under paragraph (c)</u>, a health maintenance organization issuing 118 major medical coverage through an individual or group contract 119 may not require a step-therapy protocol under the contract for a 120 covered prescription drug requested by a subscriber if:

121 1. The subscriber has previously been approved to receive 122 the prescription drug through the completion of a step-therapy 123 protocol required by a separate health coverage plan; and

124 2. The subscriber provides documentation originating from125 the health coverage plan that approved the prescription drug as

Page 5 of 7

2022 Legislature

126	described in subparagraph 1. indicating that the health coverage
127	plan paid for the drug on the subscriber's behalf during the 90
128	days immediately before the request.
129	(c)1. A health maintenance organization shall publish on
130	its website and provide to a subscriber in writing a procedure
131	for the subscriber and his or her health care provider to
132	request a protocol exemption or an appeal of the health
133	maintenance organization's denial of a protocol exemption
134	request. The procedure must include, at a minimum:
135	a. The manner in which the subscriber or health care
136	provider may request a protocol exemption, including a form to
137	request the protocol exemption.
138	b. The manner and timeframe in which the health
139	maintenance organization authorizes or denies a protocol
140	exemption request, which must occur within a reasonable time.
141	c. The manner and timeframe in which the subscriber or
142	health care provider may appeal the health maintenance
143	organization's denial of a protocol exemption request.
144	2. An authorization of a protocol exemption request must
145	specify the approved prescription drug, medical procedure, or
146	course of treatment. A denial of a protocol exemption request
147	must include a written explanation of the reason for the denial,
148	the clinical rationale that supports the denial, and the
149	procedure for appealing the health maintenance organization's
150	denial.

Page 6 of 7

FLORIDA	HOUSE	OF REPF	RESENTA	TIVES
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ENROLLED **HB 459**

2022 Legislature

151	3. A health maintenance organization may request relevant
152	medical records in support of a protocol exemption request.
153	(d) (c) This subsection does not require a health
154	maintenance organization to add a drug to its prescription drug
155	formulary or to cover a prescription drug that the health
156	maintenance organization does not otherwise cover.
157	Section 3. This act shall take effect July 1, 2022.

Page 7 of 7