1	A bill to be entitled
2	An act relating to step-therapy protocols; amending s.
3	627.42393, F.S.; providing definitions; requiring
4	health insurers to publish on their websites and
5	provide to their insureds specified information;
6	requiring health insurers to grant or deny protocol
7	exemption requests and respond to appeals; providing
8	requirements for granting and denying protocol
9	exemption requests; authorizing health insurers to
10	request specified documentation under certain
11	circumstances; amending s. 641.31, F.S.; providing
12	definitions; requiring health maintenance
13	organizations to publish on their websites and provide
14	to their subscribers specified information; requiring
15	health maintenance organizations to grant or deny
16	protocol exemption requests and respond to appeals;
17	providing requirements for granting and denying
18	protocol exemption requests; authorizing health
19	maintenance organizations to request specified
20	documentation under certain circumstances; providing
21	an effective date.
22	
23	Be It Enacted by the Legislature of the State of Florida:
24	
25	Section 1. Section 627.42393, Florida Statutes, is amended
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26	to read:
27	627.42393 Step-therapy protocol
28	(1) (2) As used in this section, the term:
29	(a) "Health coverage plan" means any of the following
30	which is currently or was previously providing major medical or
31	similar comprehensive coverage or benefits to the insured:
32	1.(a) A health insurer or health maintenance organization.
33	2.(b) A plan established or maintained by an individual
34	employer as provided by the Employee Retirement Income Security
35	Act of 1974, Pub. L. No. 93-406.
36	<u>3.(c)</u> A multiple-employer welfare arrangement as defined
37	in s. 624.437.
38	<u>4.(d)</u> A governmental entity providing a plan of self-
39	insurance.
40	(b) "Protocol exemption" means a determination by a health
41	insurer to authorize the use of another prescription drug,
42	medical procedure, or course of treatment prescribed or
43	recommended by the treating health care provider for the
44	insured's condition rather than the one specified by the health
45	insurer's step-therapy protocol.
46	(c) "Step-therapy protocol" means a written protocol that
47	specifies the order in which certain prescription drugs, medical
48	procedures, or courses of treatment must be used to treat an
49	insured's condition.
50	(2) (1) A health insurer issuing a major medical individual
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51 or group policy may not require a step-therapy protocol under 52 the policy for a covered prescription drug requested by an 53 insured if:

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

57 (b) The insured provides documentation originating from 58 the health coverage plan that approved the prescription drug as 59 described in paragraph (a) indicating that the health coverage 60 plan paid for the drug on the insured's behalf during the 90 61 days immediately before the request.

62 (3) (a) A health insurer shall publish on its website and provide to an insured in writing a procedure for the insured and 63 his or her health care provider to request a protocol exemption 64 65 or an appeal of the health insurer's action on a protocol 66 exemption request. The procedure must include, at a minimum: 67 1. The manner in which an insured or health care provider 68 may request a protocol exemption, including a form. 69 2. The manner and timeframe in which the health insurer 70 will authorize or deny a protocol exemption request, which must 71 occur within a reasonable time. 72 The manner and timeframe in which to appeal the health 3.

73 insurer's action on a request.

74 (b) An authorization of the request must specify the
 75 approved prescription drug, medical procedure, or course of

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76	treatment. A denial of the request must include a written
77	explanation of the reason for the denial, the clinical rationale
78	that supports the denial, and the procedure for appealing the
79	health insurer's action.
80	(c) A health insurer may request relevant medical records
81	in support of a protocol exemption request.
82	Section 2. Subsection (46) of section 641.31, Florida
83	Statutes, is amended to read:
84	641.31 Health maintenance contracts
85	(46) $(a)$ (b) As used in this subsection, the term:
86	1. "Health coverage plan" means any of the following which
87	previously provided or is currently providing major medical or
88	similar comprehensive coverage or benefits to the subscriber:
89	<u>a.</u> 1. A health insurer or health maintenance organization. $\cdot$
90	b.2. A plan established or maintained by an individual
91	employer as provided by the Employee Retirement Income Security
92	Act of 1974, Pub. L. No. 93-406 <u>.</u> +
93	c.3. A multiple-employer welfare arrangement as defined in
94	s. 624.437 <u>.; or</u>
95	<u>d.</u> 4. A governmental entity providing a plan of self-
96	insurance.
97	2. "Protocol exemption" means a determination by a health
98	maintenance organization to authorize the use of another
99	prescription drug, medical procedure, or course of treatment
100	prescribed or recommended by the treating health care provider
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101 for the subscriber's condition rather than the one specified by 102 the health maintenance organization's step-therapy protocol. 103 3. "Step-therapy protocol" means a written protocol that specifies the order in which certain prescription drugs, medical 104 procedures, or courses of treatment must be used to treat a 105 106 subscriber's condition. 107 (b) (a) In addition to the protocol exemptions granted 108 under paragraph (c), a health maintenance organization issuing 109 major medical coverage through an individual or group contract may not require a step-therapy protocol under the contract for a 110 covered prescription drug requested by a subscriber if: 111 112 1. The subscriber has previously been approved to receive 113 the prescription drug through the completion of a step-therapy 114 protocol required by a separate health coverage plan; and 115 The subscriber provides documentation originating from 2. 116 the health coverage plan that approved the prescription drug as 117 described in subparagraph 1. indicating that the health coverage 118 plan paid for the drug on the subscriber's behalf during the 90 days immediately before the request. 119 120 (c)1. A health maintenance organization shall publish on its website and provide to a subscriber in writing a procedure 121 122 for the subscriber and his or her health care provider to request a protocol exemption or an appeal of the health 123 124 maintenance organization's action on a protocol exemption 125 request. The procedure must include, at a minimum: Page 5 of 6

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126 The manner in which a subscriber or health care a. 127 provider may request a protocol exemption, including a form. 128 The manner and timeframe in which the health b. 129 maintenance organization will authorize or deny a protocol 130 exemption request, which must occur within a reasonable time. 131 c. The manner and timeframe in which to appeal the health 132 maintenance organization's action on a request. 133 2. An authorization of the request must specify the approved prescription drug, medical procedure, or course of 134 135 treatment. A denial of the request must include a written 136 explanation of the reason for the denial, the clinical rationale 137 that supports the denial, and the procedure for appealing the 138 health maintenance organization's action. 139 3. A health maintenance organization may request relevant 140 medical records in support of a protocol exemption request. 141 Section 3. This act shall take effect July 1, 2021.

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