1 A bill to be entitled 2 An act relating to health insurance coverage; amending 3 s. 627.4239, F.S.; defining the terms "associated 4 condition" and "health care provider"; prohibiting 5 health maintenance organizations from excluding 6 coverage for certain drugs on a specified ground; 7 prohibiting insurers and health maintenance 8 organizations of certain individual and group health 9 insurance policies and health maintenance contracts 10 from requiring, before certain drugs are covered, that 11 an insured or subscriber undergo a step-therapy 12 protocol or step-therapy override determination; providing applicability; prohibiting such insurers and 13 14 health maintenance organizations from excluding 15 coverage for certain drugs on a specified ground; 16 requiring coverage for specified services; amending 17 ss. 627.42393 and 641.31, F.S.; revising and providing definitions; requiring health coverage plans to 18 19 provide on their websites an easily accessible process 20 for requests for a step-therapy protocol override 21 determination under certain circumstances; providing 22 requirements and timeframes for the determination; 23 requiring health coverage plans to grant requests to override step-therapy protocols under certain 24 25 circumstances; requiring health coverage plans to

Page 1 of 15

CODING: Words stricken are deletions; words underlined are additions.

2020

	Dage 2 of 15
50	cancer
49	627.4239 Coverage for use of drugs in treatment of
48	to read:
47	Section 1. Section 627.4239, Florida Statutes, is amended
46	
45	Be It Enacted by the Legislature of the State of Florida:
44	
43	effective date.
42	items under certain circumstances; providing an
41	authorization requirements for certain procedures and
40	organizations from imposing additional prior
39	641.3156, F.S.; prohibiting health maintenance
38	ineligibility under certain circumstances; amending s.
37	denying at any time a claim because of subscriber
36	health maintenance organizations from retroactively
35	circumstances; amending s. 641.3155, F.S.; prohibiting
34	for certain procedures and items under certain
33	imposing additional prior authorization requirements
32	circumstances; prohibiting health insurers from
31	insured ineligibility at any time under certain
30	insurers from retroactively denying a claim because of
29	amending s. 627.6131, F.S.; prohibiting health
28	under certain circumstances; providing construction;
27	by an insured's or subscriber's health care provider
26	authorize coverage for a prescription drug prescribed

Page 2 of 15

CODING: Words stricken are deletions; words <u>underlined</u> are additions.

DEFINITIONS.-As used in this section, the term: 51 (1) 52 "Associated condition" means a symptom or side effect (a) 53 that: 54 1. Is associated with a particular cancer at a particular 55 stage or with the treatment of that cancer. 56 2. In the judgment of a health care provider, will further 57 jeopardize the health of a patient if left untreated. As used in 58 this subparagraph, the term "health care provider" means a 59 physician licensed under chapter 458, chapter 459, or chapter 60 461; a physician assistant licensed under chapter 458 or chapter 459; an advanced practice registered nurse licensed under 61 62 chapter 464; or a dentist licensed under chapter 466. (b) (a) "Medical literature" means scientific studies 63 64 published in a United States peer-reviewed national professional 65 journal. 66 (c) (b) "Standard reference compendium" means authoritative 67 compendia identified by the Secretary of the United States 68 Department of Health and Human Services and recognized by the 69 federal Centers for Medicare and Medicaid Services. 70 (2) COVERAGE FOR TREATMENT OF CANCER.-71 (a) An insurer or a health maintenance organization may 72 not exclude coverage in any individual or group health insurance policy or health maintenance contract issued, amended, 73 74 delivered, or renewed in this state which covers the treatment 75 of cancer for any drug prescribed for the treatment of cancer on Page 3 of 15

CODING: Words stricken are deletions; words underlined are additions.

76 the ground that the drug is not approved by the United States 77 Food and Drug Administration for a particular indication, if 78 that drug is recognized for treatment of that indication in a 79 standard reference compendium or recommended in the medical 80 literature. 81 (b) Coverage for a drug required by this section also 82 includes the medically necessary services associated with the 83 administration of the drug. COVERAGE FOR TREATMENT OF STAGE 4 METASTATIC CANCER 84 (3) 85 AND ASSOCIATED CONDITIONS.-In any individual or group health insurance policy or 86 (a) 87 health maintenance contract issued, amended, delivered, or 88 renewed in this state which covers the treatment of a particular 89 stage 4 metastatic cancer and its associated conditions, an 90 insurer or a health maintenance organization may not require 91 that, before a drug prescribed for the treatment is covered, the 92 insured or subscriber undergo a step-therapy protocol or step-93 therapy override determination under s. 627.42393 or s. 94 641.31(46). 95 (b) Paragraph (a) applies to a drug that is recognized for 96 the treatment of such stage 4 metastatic cancer or its 97 associated conditions, as applicable, in a standard reference 98 compendium or that is recommended in the medical literature. The 99 insurer or the health maintenance organization may not exclude 100 coverage for such drug on the ground that the drug is not

Page 4 of 15

CODING: Words stricken are deletions; words underlined are additions.

approved by the United States Food and Drug Administration for

such stage 4 metastatic cancer or its associated conditions, as

HB 373

applicable.

(b)

(C)

(d)

contract.

101

102

103

104

105

106

107

108

109

110

111

112

113

114

115

116

117

118

119

120

121

122

123

124

(4) COVERAGE FOR SERVICES ASSOCIATED WITH DRUG ADMINISTRATION.-Coverage for a drug required under this section includes the medically necessary services associated with the administration of the drug. (5) (3) APPLICABILITY AND SCOPE. - This section may not be construed to: (a) Alter any other law with regard to provisions limiting coverage for drugs that are not approved by the United States Food and Drug Administration. Require coverage for any drug if the United States Food and Drug Administration has determined that the use of the drug is contraindicated. Require coverage for a drug that is not otherwise approved for any indication by the United States Food and Drug Administration. Affect the determination as to whether particular levels, dosages, or usage of a medication associated with bone marrow transplant procedures are covered under an individual or group health insurance policy or health maintenance organization Apply to specified disease or supplemental policies.

125

(e)

(f) (4) Nothing in this section is intended, Expressly or

Page 5 of 15

CODING: Words stricken are deletions; words underlined are additions.

hb0373-00

126	by implication, to create, impair, alter, limit, modify,
127	enlarge, abrogate, prohibit, or withdraw any authority to
128	provide reimbursement for drugs used in the treatment of any
129	other disease or condition.
130	Section 2. Section 627.42393, Florida Statutes, is amended
131	to read:
132	627.42393 Step-therapy protocol
133	(1) (2) As used in this section, the term:
134	(a) "Health coverage plan" means any of the following
135	which is currently or was previously providing major medical or
136	similar comprehensive coverage or benefits to the insured:
137	<u>1.(a)</u> A health insurer <u>as defined in s. 627.42392</u> or
138	health maintenance organization.
139	2.(b) A plan established or maintained by an individual
140	employer as provided by the Employee Retirement Income Security
141	Act of 1974, Pub. L. No. 93-406.
142	<u>3.(c)</u> A multiple-employer welfare arrangement as defined
143	in s. 624.437.
144	<u>4.(d)</u> A governmental entity providing a plan of self-
145	insurance.
146	(b) "Step-therapy override determination" means a
147	determination by a health coverage plan that in a particular
148	situation a step-therapy protocol should apply or it should be
149	overridden in favor of immediate coverage of the health care
150	provider's selected prescription drug.

Page 6 of 15

CODING: Words stricken are deletions; words <u>underlined</u> are additions.

151 (c) "Step-therapy protocol" means a protocol or program 152 that establishes the specific sequence in which prescription 153 drugs determined as medically appropriate for an insured for a 154 specified medical condition are covered by a health coverage 155 plan.

156 <u>(2)(1)</u> A health <u>coverage plan under</u> insurer issuing a 157 major medical individual or group policy may not require a step-158 therapy protocol under the policy for a covered prescription 159 drug requested by an 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

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

168 (3) (a) If coverage of a prescription drug for the 169 treatment of a medical condition is restricted for use by a 170 health coverage plan through the use of a step-therapy protocol, 171 the health coverage plan must provide a clear and convenient 172 process for an insured and health care provider to request a step-therapy override determination. This process must be made 173 174 easily accessible on the health coverage plan's website. The 175 health coverage plan must provide a prescription drug for

Page 7 of 15

CODING: Words stricken are deletions; words underlined are additions.

2020

176	treatment of the insured's medical condition at least until the
177	step-therapy override determination is made.
178	(b) The health coverage plan must base the step-therapy
179	override determination on a review of the insured's or health
180	care provider's request for an override and the rationale and
181	documentation supporting the request.
182	(c)1. When an insured or health care provider submits a
183	request for a step-therapy override determination or submits an
184	appeal of a step-therapy override determination decision, the
185	health coverage plan must grant or deny the request or appeal
186	within 24 hours after the submission in an urgent care situation
187	and within 2 business days in a nonurgent care situation.
188	2. If the health coverage plan fails to respond in
189	accordance with the timeframe established in subparagraph 1.,
190	the request or appeal shall be deemed approved.
191	(d) A health coverage plan must grant a request to
192	override a step-therapy protocol in favor of the health care
193	provider's selected prescription drug for any of the following
194	reasons:
195	1. The prescription drug required under the step-therapy
196	protocol is contraindicated, or it is not in the insured's best
197	interest because the drug will likely:
198	a. Cause a significant barrier to the insured's adherence
199	to, or compliance with, the insured's plan of care.
200	b. Be ineffective, based on the insured's medical history
	Page 8 of 15

CODING: Words stricken are deletions; words underlined are additions.

2020

201	and the clinical evidence of the known characteristics of the
202	prescription drug regimen.
203	c. Cause an adverse reaction or physical or mental harm to
204	the insured, including a worsened comorbid condition or a
205	decrease in the insured's ability to achieve or maintain
206	reasonable functional ability in performing daily activities.
207	2. The insured has tried, under his or her current health
208	coverage plan, the required prescription drug or another
209	prescription drug that is in the same pharmacologic class or
210	that has the same mechanism of action, and such prescription
211	drug lacked efficacy or effectiveness or adversely affected the
212	insured.
213	3. The insured is stable on the health care provider's
214	selected prescription drug for the medical condition under
215	consideration.
216	(e) Upon granting a request to override a step-therapy
217	protocol in favor of the health care provider's selected
218	prescription drug, the health coverage plan must authorize
219	immediate coverage of the selected prescription drug if the
220	health coverage plan covers such prescription drug.
221	(4) This section does not prevent a health coverage plan
222	from requiring an insured to try a generic equivalent before
223	providing coverage for the equivalent brand-name prescription
224	drug.
225	<u>(5)</u> This section does not require a health <u>coverage</u>
	Page 9 of 15

CODING: Words stricken are deletions; words underlined are additions.

226	<u>plan</u> insurer to add a drug to its prescription drug formulary or
227	to cover a prescription drug that the <u>health coverage plan</u>
228	insurer does not otherwise cover.
229	Section 3. Subsection (11) of section 627.6131, Florida
230	Statutes, is amended, and subsection (20) is added to that
231	section, to read:
232	627.6131 Payment of claims
233	(11) A health insurer may not retroactively deny a claim
234	because of insured ineligibility <u>:</u>
235	(a) At any time, if the health insurer has confirmed
236	insured eligibility at the time of treatment or has granted
237	prior authorization for a treatment.
238	(b) Except as provided in paragraph (a), more than 1 year
239	after the date of payment of the claim.
240	(20) A health insurer may not impose any additional prior
241	authorization requirement with respect to a surgical or an
242	otherwise invasive procedure and with respect to an item
243	furnished as part of such surgical or invasive procedure, if
244	such procedure or item is furnished:
245	(a) During the perioperative period of another procedure
246	for which prior authorization from the health insurer was
247	received.
248	(b) After the prior authorization described in paragraph
249	(a) was received.
250	Section 4. Subsection (46) of section 641.31, Florida
	Page 10 of 15

CODING: Words stricken are deletions; words <u>underlined</u> are additions.

FLORIDA HOUSE OF	REPRESENTATIVES
------------------	-----------------

251	Statutes, is amended to read:
252	641.31 Health maintenance contracts
253	(46) <u>(a)</u> As used in this subsection, the term:
254	1. "Health coverage plan" means any of the following which
255	previously provided or is currently providing major medical or
256	similar comprehensive coverage or benefits to the subscriber:
257	<u>a.1. A health insurer as defined in s. 627.42392</u> or health
258	maintenance organization;
259	<u>b.</u> 2. A plan established or maintained by an individual
260	employer as provided by the Employee Retirement Income Security
261	Act of 1974, Pub. L. No. 93-406;
262	c.3. A multiple-employer welfare arrangement as defined in
263	s. 624.437; or
264	<u>d.</u> 4. A governmental entity providing a plan of self-
265	insurance.
266	2. "Step-therapy override determination" means a
267	determination by a health coverage plan that in a particular
268	situation a step-therapy protocol should apply or it should be
269	overridden in favor of immediate coverage of the health care
270	provider's selected prescription drug.
271	3. "Step-therapy protocol" means a protocol or program
272	that establishes the specific sequence in which prescription
273	drugs determined as medically appropriate for a subscriber for a
274	specified medical condition are covered by a health coverage
275	plan.

Page 11 of 15

CODING: Words stricken are deletions; words <u>underlined</u> are additions.

276 (b) (a) A health <u>coverage plan under a maintenance</u> 277 organization issuing major medical coverage through an 278 individual or group contract may not require a step-therapy 279 protocol under the contract for a covered prescription drug 280 requested by a subscriber if:

The subscriber 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

284 2. The subscriber provides documentation originating from 285 the health coverage plan that approved the prescription drug as 286 described in subparagraph 1. indicating that the health coverage 287 plan paid for the drug on the subscriber's behalf during the 90 288 days immediately before the <u>current</u> request.

289 (c)1. If coverage of a prescription drug for the treatment 290 of a medical condition is restricted for use by a health 291 coverage plan through the use of a step-therapy protocol, the 292 health coverage plan must provide a clear and convenient process 293 for a subscriber and health care provider to request a step-294 therapy override determination. This process must be made easily 295 accessible on the health coverage plan's website. The health coverage plan must provide a prescription drug for treatment of 296 297 the subscriber's medical condition at least until the steptherapy override determination is made. 298

299 <u>2. The health coverage plan must base the step-therapy</u>
 300 <u>override determination on a review of the subscriber's or health</u>

Page 12 of 15

CODING: Words stricken are deletions; words underlined are additions.

301 care provider's request for an override and the subscriber's or 302 health care provider's rationale and documentation supporting 303 the request. 304 3.a. When a subscriber or health care provider submits a 305 request for a step-therapy override determination or submits an 306 appeal of a step-therapy override determination decision, the 307 health coverage plan must grant or deny the request or appeal 308 within 24 hours after the submission in an urgent care situation 309 and within 2 business days in a nonurgent care situation. b. If the health coverage plan fails to respond in 310 311 accordance with the timeframe established in sub-subparagraph 312 a., the request or appeal shall be deemed approved. 313 4. A health coverage plan must grant a request to override 314 a step-therapy protocol in favor of the health care provider's 315 selected prescription drug for any of the following reasons: 316 a. The prescription drug required under the step-therapy 317 protocol is contraindicated, or it is not in the subscriber's 318 best interest because the drug will likely: 319 (I) Cause a significant barrier to the subscriber's 320 adherence to, or compliance with, the subscriber's plan of care. 321 (II) Be ineffective, based on the subscriber's medical history and the clinical evidence of the known characteristics 322 323 of the prescription drug regimen. 324 Cause an adverse reaction or physical or mental harm (III) 325 to the subscriber, including a worsened comorbid condition or a

Page 13 of 15

CODING: Words stricken are deletions; words underlined are additions.

326 decrease in the subscriber's ability to achieve or maintain 327 reasonable functional ability in performing daily activities. 328 b. The subscriber has tried, under his or her current 329 health coverage plan, the required prescription drug or another 330 prescription drug that is in the same pharmacologic class or that has the same mechanism of action, and such prescription 331 332 drug lacked efficacy or effectiveness or adversely affected the subscriber. 333 334 c. The subscriber is stable on the health care provider's 335 selected prescription drug for the medical condition under 336 consideration. 337 5. Upon granting a request to override a step-therapy 338 protocol in favor of the health care provider's selected 339 prescription drug, the health coverage plan must authorize 340 immediate coverage of the selected prescription drug if the 341 health coverage plan covers such prescription drug. 342 This subsection does not prevent a health coverage (d) 343 plan from requiring a subscriber to try a generic equivalent 344 before providing coverage for the brand-name prescription drug. 345 (e) (c) This subsection does not require a health 346 maintenance organization to add a drug to its prescription drug 347 formulary or to cover a prescription drug that the health maintenance organization does not otherwise cover. 348 349 Section 5. Subsection (10) of section 641.3155, Florida 350 Statutes, is amended to read:

Page 14 of 15

CODING: Words stricken are deletions; words underlined are additions.

FLORIDA HOUSE OF REPRESENTATIV	ΕS
--------------------------------	----

351 641.3155 Prompt payment of claims.-352 (10) A health maintenance organization may not 353 retroactively deny a claim because of subscriber ineligibility: 354 (a) At any time, if the health maintenance organization 355 has confirmed subscriber eligibility at the time of treatment or 356 has granted prior authorization for the treatment. 357 (b) Except as provided in paragraph (a), more than 1 year 358 after the date of payment of the claim. 359 Section 6. Subsection (4) is added to section 641.3156, 360 Florida Statutes, to read: 361 641.3156 Treatment authorization; payment of claims.-362 (4) A health maintenance organization may not impose any additional prior authorization requirement with respect to a 363 364 surgical or an otherwise invasive procedure and with respect to 365 an item furnished as part of such surgical or invasive 366 procedure, if such procedure or item is furnished: 367 (a) During the perioperative period of another procedure 368 for which prior authorization from the health maintenance 369 organization was received. 370 (b) After the prior authorization described in paragraph 371 (a) was received. 372 Section 7. This act shall take effect January 1, 2021.

Page 15 of 15

CODING: Words stricken are deletions; words underlined are additions.