By Senator Harrell

	25-00241C-20 2020820
1	A bill to be entitled
2	An act relating to health insurance prior
3	authorization; amending s. 627.4239, F.S.; defining
4	the terms "associated condition" and "health care
5	provider"; prohibiting health maintenance
6	organizations from excluding coverage for certain
7	cancer treatment drugs; prohibiting health insurers
8	and health maintenance organizations from requiring,
9	before providing prescription drug coverage for the
10	treatment of stage 4 metastatic cancer and associated
11	conditions, that treatment has failed with a different
12	drug; providing applicability; prohibiting insurers
13	and health maintenance organizations from excluding
14	coverage for certain drugs on certain grounds;
15	revising construction; amending s. 627.42392, F.S.;
16	revising the definition of the term "health insurer";
17	defining the term "urgent care situation"; specifying
18	a requirement for the prior authorization form adopted
19	by the Financial Services Commission by rule;
20	authorizing the commission to adopt certain rules;
21	specifying requirements for, and restrictions on,
22	health insurers and pharmacy benefits managers
23	relating to prior authorization information,
24	requirements, restrictions, and changes; providing
25	applicability; specifying timeframes in which prior
26	authorization requests must be authorized or denied
27	and the patient and the patient's provider must be
28	notified; amending s. 627.42393, F.S.; defining terms;
29	requiring health insurers to provide and disclose

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30	procedures for insureds to request exceptions to step-
31	therapy protocols; specifying requirements for such
32	procedures and disclosures; requiring health insurers
33	to authorize or deny protocol exception requests and
34	respond to certain appeals within specified
35	timeframes; specifying required information in
36	authorizations and denials of such requests; requiring
37	health insurers to grant a protocol exception request
38	under specified circumstances; authorizing health
39	insurers to request certain documentation; conforming
40	provisions to changes made by the act; amending s.
41	627.6131, F.S.; prohibiting health insurers, under
42	certain circumstances, from retroactively denying a
43	claim at any time because of insured ineligibility;
44	prohibiting health insurers from imposing an
45	additional prior authorization requirement with
46	respect to certain surgical or invasive procedures or
47	certain items; amending s. 641.31, F.S.; defining
48	terms; requiring health maintenance organizations to
49	provide and disclose procedures for subscribers to
50	request exceptions to step-therapy protocols;
51	specifying requirements for such procedures and
52	disclosures; requiring health maintenance
53	organizations to authorize or deny protocol exception
54	requests and respond to certain appeals within
55	specified timeframes; specifying required information
56	in authorizations and denials of such requests;
57	requiring health maintenance organizations to grant a
58	protocol exception request under specified

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59	circumstances; authorizing health maintenance
60	organizations to request certain documentation;
61	conforming provisions to changes made by the act;
62	amending s. 641.3155, F.S.; prohibiting health
63	maintenance organizations, under certain
64	circumstances, from retroactively denying a claim at
65	any time because of subscriber ineligibility; amending
66	s. 641.3156, F.S.; prohibiting health maintenance
67	organizations from imposing an additional prior
68	authorization requirement with respect to certain
69	surgical or invasive procedures or certain items;
70	providing an effective date.
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72	Be It Enacted by the Legislature of the State of Florida:
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74	Section 1. Section 627.4239, Florida Statutes, is amended
75	to read:
76	627.4239 Coverage for use of drugs in treatment of cancer
77	(1) DEFINITIONS.—As used in this section, the term:
78	(a) "Associated condition" means a symptom or side effect
79	that:
80	1. Is associated with a particular cancer at a particular
81	stage or with the treatment of that cancer; and
82	2. In the judgment of a health care provider, will further
83	jeopardize the health of a patient if left untreated. As used in
84	this subparagraph, the term "health care provider" means a
85	physician licensed under chapter 458, chapter 459, or chapter
86	461, a physician assistant licensed under chapter 458 or chapter
87	459, an advanced practice registered nurse licensed under

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88	chapter 464, or a dentist licensed under chapter 466.
89	(b) (a) "Medical literature" means scientific studies
90	published in a United States peer-reviewed national professional
91	journal.
92	<u>(c)</u> "Standard reference compendium" means authoritative
93	compendia identified by the Secretary of the United States
94	Department of Health and Human Services and recognized by the
95	federal Centers for Medicare and Medicaid Services.
96	(2) COVERAGE FOR TREATMENT OF CANCER
97	(a) An insurer <u>or a health maintenance organization</u> may not
98	exclude coverage in any individual or group <u>health</u> insurance
99	policy or health maintenance contract issued, amended,
100	delivered, or renewed in this state which covers the treatment
101	of cancer for any drug prescribed for the treatment of cancer on
102	the ground that the drug is not approved by the United States
103	Food and Drug Administration for a particular indication, if
104	that drug is recognized for treatment of that indication in a
105	standard reference compendium or recommended in the medical
106	literature.
107	(b) Coverage for a drug required by this section also
108	includes the medically necessary services associated with the
109	administration of the drug.
110	(3) COVERAGE FOR TREATMENT OF STAGE 4 METASTATIC CANCER AND
111	ASSOCIATED CONDITIONS
112	(a) An insurer or a health maintenance organization may not
113	require in any individual or group health insurance policy or
114	health maintenance contract issued, amended, delivered, or
115	renewed in this state which covers the treatment of stage 4
116	metastatic cancer and its associated conditions that, before a

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117	drug prescribed for the treatment is covered, the insured or
118	subscriber fail or have previously failed to respond
119	successfully to a different drug.
120	(b) Paragraph (a) applies to a drug that is recognized for
121	the treatment of such stage 4 metastatic cancer or its
122	associated conditions, as applicable, in a standard reference
123	compendium or that is recommended in the medical literature. The
124	insurer or health maintenance organization may not exclude
125	coverage for such drug on the ground that the drug is not
126	approved by the United States Food and Drug Administration for
127	such stage 4 metastatic cancer or its associated conditions, as
128	applicable.
129	(4) COVERAGE FOR SERVICES ASSOCIATED WITH DRUG
130	ADMINISTRATIONCoverage for a drug required by this section
131	also includes the medically necessary services associated with
132	the administration of the drug.
133	(5)-(3) APPLICABILITY AND SCOPE.—This section may not be
134	construed to:
135	(a) Alter any other law with regard to provisions limiting
136	coverage for drugs that are not approved by the United States
137	Food and Drug Administration, except for drugs for the treatment
138	of stage 4 metastatic cancer or its associated conditions.
139	(b) Require coverage for any drug, except for a drug for
140	the treatment of stage 4 metastatic cancer or its associated
141	<u>conditions,</u> if the United States Food and Drug Administration
142	has determined that the use of the drug is contraindicated.
143	(c) Require coverage for a drug that is not otherwise
144	approved for any indication by the United States Food and Drug
145	Administration, except for a drug for the treatment of stage 4

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146	metastatic cancer or its associated conditions.
147	(d) Affect the determination as to whether particular
148	levels, dosages, or usage of a medication associated with bone
149	marrow transplant procedures are covered under an individual or
150	group health insurance policy or health maintenance organization
151	contract.
152	(e) Apply to specified disease or supplemental policies.
153	<u>(f)</u> (4) Nothing in this section is intended, Expressly or by
154	implication, to create, impair, alter, limit, modify, enlarge,
155	abrogate, prohibit, or withdraw any authority to provide
156	reimbursement for drugs used in the treatment of any other
157	disease or condition.
158	Section 2. Section 627.42392, Florida Statutes, is amended
159	to read:
160	627.42392 Prior authorization
161	(1) As used in this section, the term:
162	(a) "Health insurer" means an authorized insurer offering
163	an individual or group health insurance policy that provides
164	<u>major medical or similar comprehensive coverage</u> health insurance
165	as defined in s. 624.603 , a managed care plan as defined in s.
166	409.962(10), or a health maintenance organization as defined in
167	s. 641.19(12).
168	(b) "Urgent care situation" has the same meaning as
169	provided in s. 627.42393(1).
170	(2) Notwithstanding any other provision of law, effective
171	January 1, 2017, or six (6) months after the effective date of
172	the rule adopting the prior authorization form, whichever is
173	later, a health insurer, or a pharmacy benefits manager on
174	behalf of the health insurer, which does not provide an
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176	providers, shall only use the prior authorization form that has
177	been approved by the Financial Services Commission for granting
178	a prior authorization for a medical procedure, course of
179	treatment, or prescription drug benefit. Such form may not
180	exceed two pages in length, excluding any instructions or
181	guiding documentation, and must include all clinical
182	documentation necessary for the health insurer to make a
183	decision. At a minimum, the form must include:
184	(a) (1) Sufficient patient information to identify the
185	member, <u>his or her</u> date of birth, full name, and Health Plan ID
186	number;
187	(b) (2) The provider's provider name, address, and phone
188	number;
189	(c)-(3) The medical procedure, course of treatment, or
190	prescription drug benefit being requested, including the medical
191	reason therefor, and all services tried and failed;
192	(d) (4) Any laboratory documentation required; and
193	<u>(e)</u> An attestation that all information provided is true
194	and accurate.
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196	The form, whether in electronic or paper format, must require
197	only information that is necessary for the determination of
198	medical necessity of, or coverage for, the requested medical
199	procedure, course of treatment, or prescription drug benefit.
200	The commission may adopt rules prescribing such necessary
201	information.
202	(3) The Financial Services Commission <u>,</u> in consultation with
203	the Agency for Health Care Administration <u>,</u> shall adopt by rule

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204	guidelines for all prior authorization forms which ensure the
205	general uniformity of such forms.
206	(4) Electronic prior authorization approvals do not
207	preclude benefit verification or medical review by the insurer
208	under either the medical or pharmacy benefits.
209	(5) A health insurer, or a pharmacy benefits manager on
210	behalf of the health insurer, shall provide upon request the
211	following information in writing or in an electronic format and
212	publish it on a publicly accessible website:
213	(a) Detailed descriptions in clear, easily understandable
214	language of the requirements for, and restrictions on, obtaining
215	prior authorization for coverage of a medical procedure, course
216	of treatment, or prescription drug. Clinical criteria must be
217	described in language a health care provider can easily
218	understand.
219	(b) Prior authorization forms.
220	(6) A health insurer, or a pharmacy benefits manager on
221	behalf of the health insurer, may not implement any new
222	requirements or restrictions or make changes to existing
223	requirements or restrictions on obtaining prior authorization
224	unless:
225	(a) The changes have been available on a publicly
226	accessible website for at least 60 days before they are
227	implemented; and
228	(b) Policyholders and health care providers who are
229	affected by the new requirements and restrictions or changes to
230	the requirements and restrictions are provided with a written
231	notice of the changes at least 60 days before they are
232	implemented. Such notice may be delivered electronically or by

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233	other means as agreed to by the insured or the health care
234	provider.
235	
236	This subsection does not apply to the expansion of health care
237	services coverage.
238	(7) A health insurer, or a pharmacy benefits manager on
239	behalf of the health insurer, must authorize or deny a prior
240	authorization request and notify the patient and the patient's
241	treating health care provider of the decision within:
242	(a) Seventy-two hours after receiving a completed prior
243	authorization form for nonurgent care situations.
244	(b) Twenty-four hours after receiving a completed prior
245	authorization form for urgent care situations.
246	Section 3. Section 627.42393, Florida Statutes, is amended
247	to read:
248	627.42393 Step-therapy protocol restrictions and
249	exceptions
250	(1) DEFINITIONSAs used in this section, the term:
251	(a) "Health coverage plan" means any of the following which
252	is currently or was previously providing major medical or
253	similar comprehensive coverage or benefits to the insured:
254	1. A health insurer or health maintenance organization.
255	2. A plan established or maintained by an individual
256	employer as provided by the Employee Retirement Income Security
257	Act of 1974, Pub. L. No. 93-406.
258	3. A multiple-employer welfare arrangement as defined in s.
259	<u>624.437.</u>
260	4. A governmental entity providing a plan of self-
261	insurance.

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262	(b) "Health insurer" has the same meaning as provided in s.
263	<u>627.42392.</u>
264	(c) "Preceding prescription drug or medical treatment"
265	means a prescription drug, medical procedure, or course of
266	treatment that must be used pursuant to a health insurer's step-
267	therapy protocol as a condition of coverage under a health
268	insurance policy to treat an insured's condition.
269	(d) "Protocol exception" means a determination by a health
270	insurer that a step-therapy protocol is not medically
271	appropriate or indicated for treatment of an insured's
272	condition, and the health insurer authorizes the use of another
273	medical procedure, course of treatment, or prescription drug
274	prescribed or recommended by the treating health care provider
275	for the insured's condition.
276	(e) "Step-therapy protocol" means a written protocol that
277	specifies the order in which certain medical procedures, courses
278	of treatment, or prescription drugs must be used to treat an
279	insured's condition.
280	(f) "Urgent care situation" means an injury or condition of
281	an insured which, if medical care and treatment are not provided
282	earlier than the time the medical profession generally considers
283	reasonable for a nonurgent situation, in the opinion of the
284	insured's treating physician, physician assistant, or advanced
285	practice registered nurse, would:
286	1. Seriously jeopardize the insured's life, health, or
287	ability to regain maximum function; or
288	2. Subject the insured to severe pain that cannot be
289	adequately managed.
290	(2) STEP-THERAPY PROTOCOL RESTRICTIONSIn addition to
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291	protocol exceptions granted under subsection (3) and the
292	restriction under s. 627.4239(3), a health insurer issuing a
293	major medical individual or group policy may not require a step-
294	therapy protocol under the policy for a covered prescription
295	drug requested by an insured if:
296	(a) The insured has previously been approved to receive the
297	prescription drug through the completion of a step-therapy
298	protocol required by a separate health coverage plan; and
299	(b) The insured provides documentation originating from the
300	health coverage plan that approved the prescription drug as
301	described in paragraph (a) indicating that the health coverage
302	plan paid for the drug on the insured's behalf during the 90
303	days immediately before the request.
304	(3) STEP-THERAPY PROTOCOL EXCEPTIONS; REQUIREMENTS AND
305	PROCEDURES
306	(a) A health insurer shall publish on its website and
307	provide to an insured in writing a procedure for the insured and
308	his or her health care provider to request a protocol exception.
309	The procedure must include:
310	1. The manner in which an insured or health care provider
311	may request a protocol exception.
312	2. The manner and timeframe in which the health insurer is
313	required to authorize or deny a protocol exception request or to
314	respond to an appeal of the health insurer's authorization or
315	denial of a request.
316	3. The conditions under which the protocol exception
317	request must be granted.
318	(b)1. A health insurer must authorize or deny a protocol
319	exception request or respond to an appeal of a health insurer's
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320	authorization or denial of a request within:
321	a. Seventy-two hours after receiving a completed prior
322	authorization form for nonurgent care situations.
323	b. Twenty-four hours after receiving a completed prior
324	authorization form for urgent care situations.
325	2. An authorization of the request must specify the
326	approved medical procedure, course of treatment, or prescription
327	drug benefits.
328	3. A denial of the request must include a detailed written
329	explanation of the reason for the denial, the clinical rationale
330	that supports the denial, and the procedure for appealing the
331	health insurer's determination.
332	(c) A health insurer must grant a protocol exception
333	request if any of the following applies:
334	1. A preceding prescription drug or medical treatment is
335	contraindicated or will likely cause an adverse reaction or
336	physical or mental harm to the insured.
337	2. A preceding prescription drug or medical treatment is
338	expected to be ineffective based on the insured's medical
339	history and the clinical evidence of the characteristics of the
340	preceding prescription drug or medical treatment.
341	3. The insured has previously received a preceding
342	prescription drug or medical treatment that is in the same
343	pharmacologic class or has the same mechanism of action and such
344	drug or treatment lacked efficacy or effectiveness or adversely
345	affected the insured.
346	4. A preceding prescription drug or medical treatment is
347	not in the insured's best interest because his or her use of the
348	drug or treatment is expected to:

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349	a. Cause a significant barrier to the insured's adherence
350	to or compliance with his or her plan of care;
351	b. Worsen the insured's medical condition that exists
352	simultaneously with, but independently of, the condition under
353	treatment; or
354	c. Decrease the insured's ability to achieve or maintain
355	his or her ability to perform daily activities.
356	5. A preceding prescription drug is an opioid and the
357	protocol exception request is for a nonopioid prescription drug
358	or treatment with a likelihood of similar or better results.
359	(d) A health insurer may request a copy of relevant
360	documentation from an insured's medical record in support of a
361	protocol exception request.
362	(2) As used in this section, the term "health coverage
363	plan" means any of the following which is currently or was
364	previously providing major medical or similar comprehensive
365	coverage or benefits to the insured:
366	(a) A health insurer or health maintenance organization.
367	(b) A plan established or maintained by an individual
368	employer as provided by the Employee Retirement Income Security
369	Act of 1974, Pub. L. No. 93-406.
370	(c) A multiple-employer welfare arrangement as defined in
371	s. 624.437.
372	(d) A governmental entity providing a plan of self-
373	insurance.
374	(4) (3) CONSTRUCTION.—This section does not require a health
375	insurer to add a drug to its prescription drug formulary or to
376	cover a prescription drug that the insurer does not otherwise
377	cover.
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378	Section 4. Subsection (11) of section 627.6131, Florida
379	Statutes, is amended, and subsection (20) is added to that
380	section, to read:
381	627.6131 Payment of claims
382	(11) A health insurer may not retroactively deny a claim
383	because of insured ineligibility <u>:</u>
384	(a) More than 1 year after the date of payment of the
385	claim <u>; or</u>
386	(b) At any time, if the health insurer verified the
387	insured's eligibility at the time of treatment or provided an
388	authorization number.
389	(20) A health insurer may not impose an additional prior
390	authorization requirement with respect to a surgical or
391	otherwise invasive procedure, or any item furnished as part of
392	the surgical or invasive procedure, if the procedure or item is
393	furnished during the perioperative period of another procedure
394	for which prior authorization was granted by the health insurer.
395	Section 5. Subsection (46) of section 641.31, Florida
396	Statutes, is amended to read:
397	641.31 Health maintenance contracts
398	(46)(a) <i>Definitions.</i> —As used in this subsection, the term:
399	1. "Health coverage plan" means any of the following which
400	is currently or was previously providing major medical or
401	similar comprehensive coverage or benefits to the subscriber:
402	a. A health insurer or health maintenance organization.
403	b. A plan established or maintained by an individual
404	employer as provided by the Employee Retirement Income Security
405	Act of 1974, Pub. L. No. 93-406.
406	c. A multiple-employer welfare arrangement as defined in s.

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407	<u>624.437.</u>
408	d. A governmental entity providing a plan of self-
409	insurance.
410	2. "Preceding prescription drug or medical treatment" means
411	a prescription drug, medical procedure, or course of treatment
412	that must be used pursuant to a health maintenance
413	organization's step-therapy protocol as a condition of coverage
414	under a health maintenance contract to treat a subscriber's
415	condition.
416	3. "Protocol exception" means a determination by a health
417	maintenance organization that a step-therapy protocol is not
418	medically appropriate or indicated for treatment of a
419	subscriber's condition, and the health maintenance organization
420	authorizes the use of another medical procedure, course of
421	treatment, or prescription drug prescribed or recommended by the
422	treating health care provider for the subscriber's condition.
423	4. "Step-therapy protocol" means a written protocol that
424	specifies the order in which certain medical procedures, courses
425	of treatment, or prescription drugs must be used to treat a
426	subscriber's condition.
427	5. "Urgent care situation" means an injury or condition of
428	a subscriber which, if medical care and treatment are not
429	provided earlier than the time the medical profession generally
430	considers reasonable for a nonurgent situation, in the opinion
431	of the subscriber's treating physician, physician assistant, or
432	advanced practice registered nurse, would:
433	a. Seriously jeopardize the subscriber's life, health, or
434	ability to regain maximum function; or
435	b. Subject the subscriber to severe pain that cannot be

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436 adequately managed.

(b) Step-therapy protocol restrictions.-In addition to protocol exceptions granted under paragraph (c) and the restriction under s. 627.4239(3), a health maintenance organization issuing major medical coverage through an individual or group contract may not require a step-therapy protocol under the contract for a covered prescription drug requested by a subscriber if:

1. 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

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

452 (c) Step-therapy protocol exceptions; requirements and 453 procedures.—

454 <u>1. A health maintenance organization shall publish on its</u>
455 <u>website and provide to a subscriber in writing a procedure for</u>
456 <u>the subscriber and his or her health care provider to request a</u>
457 <u>protocol exception. The procedure must include:</u>

458 <u>a. The manner in which a subscriber or health care provider</u>
 459 <u>may request a protocol exception.</u>

b. The manner and timeframe in which the health maintenance
 organization is required to authorize or deny a protocol
 exception request or to respond to an appeal of the health
 maintenance organization's authorization or denial of a request.
 c. The conditions under which the protocol exception

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465	request must be granted.
466	2.a. A health maintenance organization must authorize or
467	deny a protocol exception request or respond to an appeal of a
468	health maintenance organization's authorization or denial of a
469	request within:
470	(I) Seventy-two hours after receiving a completed prior
471	authorization form for nonurgent care situations.
472	(II) Twenty-four hours after receiving a completed prior
473	authorization form for urgent care situations.
474	b. An authorization of the request must specify the
475	approved medical procedure, course of treatment, or prescription
476	drug benefits.
477	c. A denial of the request must include a detailed written
478	explanation of the reason for the denial, the clinical rationale
479	that supports the denial, and the procedure for appealing the
480	health maintenance organization's determination.
481	3. A health maintenance organization must grant a protocol
482	exception request if any of the following applies:
483	a. A preceding prescription drug or medical treatment is
484	contraindicated or will likely cause an adverse reaction or
485	physical or mental harm to the subscriber.
486	b. A preceding prescription drug or medical treatment is
487	expected to be ineffective based on the subscriber's medical
488	history and the clinical evidence of the characteristics of the
489	preceding prescription drug or medical treatment.
490	c. The subscriber has previously received a preceding
491	prescription drug or medical treatment that is in the same
492	pharmacologic class or has the same mechanism of action and such
493	drug or treatment lacked efficacy or effectiveness or adversely

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494	affected the subscriber.
495	d. A preceding prescription drug or medical treatment is
496	not in the subscriber's best interest because his or her use of
497	the drug or treatment is expected to:
498	(I) Cause a significant barrier to the subscriber's
499	adherence to or compliance with his or her plan of care;
500	(II) Worsen the subscriber's medical condition that exists
501	simultaneously with, but independently of, the condition under
502	treatment; or
503	(III) Decrease the subscriber's ability to achieve or
504	maintain his or her ability to perform daily activities.
505	e. A preceding prescription drug is an opioid and the
506	protocol exception request is for a nonopioid prescription drug
507	or treatment with a likelihood of similar or better results.
508	4. A health maintenance organization may request a copy of
509	relevant documentation from a subscriber's medical record in
510	support of a protocol exception request.
511	(b) As used in this subsection, the term "health coverage
512	plan" means any of the following which previously provided or is
513	currently providing major medical or similar comprehensive
514	coverage or benefits to the subscriber:
515	1. A health insurer or health maintenance organization;
516	2. A plan established or maintained by an individual
517	employer as provided by the Employee Retirement Income Security
518	Act of 1974, Pub. L. No. 93-406;
519	3. A multiple-employer welfare arrangement as defined in s.
520	624.437; or
521	4. A governmental entity providing a plan of self-
522	insurance.
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523	(d) (c) <u>Construction.</u> This subsection does not require a
524	health maintenance organization to add a drug to its
525	prescription drug formulary or to cover a prescription drug that
526	the health maintenance organization does not otherwise cover.
527	Section 6. Subsection (10) of section 641.3155, Florida
528	Statutes, is amended to read:
529	641.3155 Prompt payment of claims
530	(10) A health maintenance organization may not
531	retroactively deny a claim because of subscriber ineligibility:
532	(a) More than 1 year after the date of payment of the
533	claim <u>; or</u>
534	(b) At any time, if the health maintenance organization
535	verified the subscriber's eligibility at the time of treatment
536	or provided an authorization number.
537	Section 7. Subsection (4) is added to section 641.3156,
538	Florida Statutes, to read:
539	641.3156 Treatment authorization; payment of claims
540	(4) A health maintenance organization may not impose an
541	additional prior authorization requirement with respect to a
542	surgical or otherwise invasive procedure, or any item furnished
543	as part of the surgical or invasive procedure, if the procedure
544	or item is furnished during the perioperative period of another
545	procedure for which prior authorization was granted by the
546	health maintenance organization.
547	Section 8. This act shall take effect January 1, 2021.

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