

1 A bill to be entitled
2 An act relating to health insurance; providing a short
3 title; amending s. 409.967, F.S.; revising provisions
4 relating to a managed care plan's prescription drug
5 formulary; providing coverage requirements for such
6 formulary; providing for appeal of certain coverage
7 decisions made by managed care plan; restricting
8 certain managed care plans from implementing
9 discriminatory benefit plans; requiring Office of
10 Insurance Regulation to issue annual report; providing
11 requirements for such report; creating ss. 627.6466
12 and 641.394, F.S., relating to fail-first protocols;
13 providing for appeal of treatment decisions made by
14 health insurers and health maintenance organizations,
15 respectively; creating ss. 627.64996 and 641.229,
16 F.S.; authorizing Office of Insurance Regulation to
17 hold certain public hearings regarding health insurers
18 and health maintenance organizations, respectively;
19 providing nondiscrimination and reporting requirements
20 for health insurers and health maintenance
21 organizations; providing for appeal of certain
22 coverage decisions made by health insurers and health
23 maintenance organizations; providing that certain
24 treatment criteria used by health insurers and health
25 maintenance organizations constitute a violation;
26 providing penalties; creating s. 627.6165, F.S.;

27 providing that certain health care insurance
 28 provisions do not abrogate an insured's general civil
 29 and common law rights; providing requirements for
 30 certain civil actions brought against an insurer;
 31 providing for application of damages and attorney fees
 32 in such actions; amending s. 641.3917, F.S.; providing
 33 requirements for certain civil actions brought against
 34 a health maintenance organization; providing for
 35 application of damages and attorney fees in such
 36 actions; providing an effective date.

37
 38 Be It Enacted by the Legislature of the State of Florida:

39
 40 Section 1. This act may be cited as the "Florida Patient
 41 Protection Act."

42 Section 2. Paragraph (c) of subsection (2) of section
 43 409.967, Florida Statutes, is amended to read:

44 409.967 Managed care plan accountability.—

45 (2) The agency shall establish such contract requirements
 46 as are necessary for the operation of the statewide managed care
 47 program. In addition to any other provisions the agency may deem
 48 necessary, the contract must require:

49 (c) Access.—

50 1. The agency shall establish specific standards for the
 51 number, type, and regional distribution of providers in managed
 52 care plan networks to ensure access to care for both adults and

53 children. Each plan must maintain a regionwide network of
54 providers in sufficient numbers to meet the access standards for
55 specific medical services for all recipients enrolled in the
56 plan. The exclusive use of mail-order pharmacies may not be
57 sufficient to meet network access standards. Consistent with the
58 standards established by the agency, provider networks may
59 include providers located outside the region. A plan may
60 contract with a new hospital facility before the date the
61 hospital becomes operational if the hospital has commenced
62 construction, will be licensed and operational by January 1,
63 2013, and a final order has issued in any civil or
64 administrative challenge. Each plan shall establish and maintain
65 an accurate and complete electronic database of contracted
66 providers, including information about licensure or
67 registration, locations and hours of operation, specialty
68 credentials and other certifications, specific performance
69 indicators, and such other information as the agency deems
70 necessary. The database must be available online to both the
71 agency and the public and have the capability to compare the
72 availability of providers to network adequacy standards and to
73 accept and display feedback from each provider's patients. Each
74 plan shall submit quarterly reports to the agency identifying
75 the number of enrollees assigned to each primary care provider.

76 2.a. If a managed care plan establishes a prescription
77 drug formulary or preferred drug list, the managed care plan
78 shall:

79 (I) Provide a broad range of therapeutic options for the
80 treatment of disease states consistent with the general needs of
81 an outpatient population. When feasible, the formulary or
82 preferred drug list shall include at least two products in a
83 therapeutic class.

84 (II) Include coverage through prior authorization for each
85 drug newly approved by the United States Food and Drug
86 Administration until the Medicaid Pharmaceutical and
87 Therapeutics Committee reviews such drug for inclusion on the
88 formulary or preferred drug list. The timing of the review must
89 comply with s. 409.91195.

90 b. Each managed care plan shall ~~must~~ publish any
91 prescribed drug formulary or preferred drug list on the plan's
92 website in a manner that is accessible to and searchable by
93 enrollees and providers. The plan shall ~~must~~ update the list
94 within 24 hours after making a change. Each plan must ensure
95 ~~that the prior authorization process for prescribed drugs is~~
96 ~~readily accessible to health care providers, including posting~~
97 ~~appropriate contact information on its website and providing~~
98 ~~timely responses to providers.~~

99 c. If a prescription drug on a formulary or preferred drug
100 list is removed or changed, the managed care plan shall permit
101 an enrollee who was receiving the drug to continue to receive
102 the drug if the provider submits a written request that
103 demonstrates that the drug is medically necessary and the
104 enrollee meets clinical criteria to receive the drug.

105 d. Each managed care plan shall have in place a medical
106 exceptions process that allows enrollees or their authorized
107 representative, which may include the prescribing health care
108 provider, to request and obtain approval of coverage for a
109 clinically appropriate prescription drug when such drug would
110 otherwise not be covered until the enrollee has satisfied a
111 prior authorization restriction, including a step therapy
112 requirement or fail-first protocol, or such drug would not be
113 covered at the prescribed number of doses.

114 e. For purposes of this paragraph, a prescription drug is
115 "clinically appropriate" to treat the enrollee's disease or
116 medical condition when the health care provider prescribing the
117 drug submits an oral or written statement stating that he or she
118 has determined that the drug is clinically appropriate based on
119 one of the following criteria:

120 (I) The number of doses available under a dose restriction
121 for the prescription drug has been ineffective in the treatment
122 of the enrollee's disease or medical condition, or, based on
123 sound clinical evidence, medical and scientific evidence, the
124 known relevant physical or mental characteristics of the
125 enrollee, and known characteristics of the drug regimen, is
126 likely to be ineffective or adversely affect the drug's
127 effectiveness or patient compliance; or

128 (II) A prescription drug alternative listed as a preferred
129 drug on the formulary or preferred drug list or required to be
130 used in accordance with step therapy requirements:

131 (A) Has been ineffective in the treatment of the
132 enrollee's disease or medical condition or, based on sound
133 clinical evidence, medical and scientific evidence, the known
134 relevant physical or mental characteristics of the enrollee, and
135 known characteristics of the drug regimen, is likely to be
136 ineffective or adversely affect the drug's effectiveness or
137 patient compliance; or

138 (B) Has caused or, based on sound clinical evidence and
139 medical and scientific evidence, is likely to cause an adverse
140 reaction or other harm to the enrollee.

141 f. Notwithstanding any other provision of this section,
142 the managed care plan must provide coverage for at least a one
143 month supply of the prescription drug that is the subject of any
144 request under this subparagraph for any new enrollee to ensure
145 continuity of coverage.

146 g. For purposes of this subparagraph, each managed care
147 plan's medical exceptions process must conform to the following
148 requirements:

149 (I) Any request for approval of coverage made verbally or
150 in writing shall be reviewed by appropriate health care
151 professionals who shall take into account the specific facts and
152 circumstances of the enrollee's disease or medical condition and
153 whose decisions shall be made using documented review criteria
154 based on sound clinical and medical and scientific evidence.

155 (II) The managed care plan shall make a decision on a
156 request and notify the enrollee or the enrollee's authorized

157 representative of the decision as quickly as the enrollee's
158 medical condition requires, but in no event later than 72 hours
159 after receipt of the request, or for circumstances in which
160 applying the standard procedure may seriously jeopardize the
161 enrollee's life, health, or ability regain maximum function, no
162 later than 24 hours after receipt of the request.

163 (III) Any denial of a request shall be provided in writing
164 to the insured or the insured's authorized representative and to
165 the insured's prescribing health care provider and shall
166 contain:

167 (A) The specific reason or reasons for the denial.

168 (B) A reference to the evidence or documentation,
169 including the clinical review criteria, clinical evidence, and
170 medical and scientific evidence considered in reaching the
171 decision.

172 (C) A description of the process and procedures for
173 requesting an appeal of the denial.

174 (IV) Any denial shall be subject to procedures established
175 by the managed care plan pursuant 42 C.F.R. Part 438, Subpart F.

176 (V) The managed care plan shall provide coverage of a
177 prescription drug that is subject of a request made pursuant to
178 sub-sub-subparagraph (I) during the entire review process as
179 long as the prescription drug continues to be prescribed for the
180 insured and is considered safe for the treatment of the
181 insured's medical condition, until a final decision is made on
182 the appeal.

183 h. In the case of an exception granted under this
 184 paragraph, a managed care plan shall not establish a copayment,
 185 coinsurance, or other cost-sharing requirement that exceeds the
 186 amount or percentage applicable to preferred brand name drugs.

187 i. A managed care plan shall provide coverage of a drug
 188 approved pursuant to the process established under this
 189 paragraph to the enrollee for as long as the prescription drug
 190 continues to be prescribed for that enrollee and is considered
 191 safe for the treatment of the enrollee's medical condition and
 192 the enrollee remains continuously enrolled in the plan.

193 j. Each managed care plan shall maintain data and upon
 194 request, make available to the agency, the following information
 195 with respect to medical exceptions requests made under this
 196 paragraph:

197 (I) The total number of medical exceptions requests.

198 (II) The number of medical exceptions requests approved
 199 and denied.

200 (III) Any other information the agency may request.

201 k. When medications for the treatment of a medical
 202 condition are restricted for use by a managed care plan through
 203 a step-therapy or fail-first protocol, the prescribing physician
 204 shall have access to a clear and convenient process to request
 205 an override of such restriction from the managed care plan. The
 206 managed care plan shall grant an override of the protocol within
 207 24 hours under the following circumstances:

208 (I) The prescribing provider recommends, based on sound

209 clinical evidence, that the preferred treatment required under
 210 step-therapy or fail-first protocol has been ineffective in the
 211 treatment of the enrollee's disease or medical condition; or

212 (II) Based on sound clinical evidence or medical and
 213 scientific evidence, the prescribing provider believes that the
 214 preferred treatment required under the step-therapy or fail-
 215 first protocol:

216 (A) Is expected or is likely to be ineffective given the
 217 known relevant physical or mental characteristics and medical
 218 history of the enrollee and the known characteristics of the
 219 drug regimen; or

220 (B) Will cause or will likely cause an adverse reaction or
 221 other physical harm to the enrollee.

222
 223 If the prescribing provider allows the enrollee to enter the
 224 step-therapy or fail-first protocol recommended by the managed
 225 care plan, the duration of the step-therapy or fail-first
 226 protocol may not exceed a period deemed appropriate by the
 227 provider. If prescribing provider deems the treatment clinically
 228 ineffective, the enrollee is entitled to receive the recommended
 229 course of therapy without requiring the prescribing provider to
 230 seek approval for an override of the step-therapy or fail-first
 231 protocol.

232 1. For enrollees ~~Medicaid recipients~~ diagnosed with
 233 hemophilia who have been prescribed anti-hemophilic-factor
 234 replacement products, the agency shall provide for those

235 products and hemophilia overlay services through the agency's
236 hemophilia disease management program.

237 3. Notwithstanding any provision of state or federal law,
238 no managed care plan shall use treatment guidelines, coverage
239 rules, or criteria for treatment authorization that restrict
240 payment for medically appropriate treatment prescribed by a
241 licensed physician and agreed to by a fully informed individual
242 or his or her advance medical directive or medical power of
243 attorney. Refusing coverage for medically necessary treatment to
244 be rendered to an insured based solely on the insured's life
245 expectancy or the fact that the insured is diagnosed with a
246 terminal condition is a violation of this paragraph.

247 4. Forms to request a prior authorization shall be made
248 available electronically by the agency and on the website of the
249 managed care plan, and managed care plans, and their fiscal
250 agents or intermediaries, must accept prior authorization
251 requests for any service electronically.

252 ~~5.4.~~ Managed care plans serving children in the care and
253 custody of the Department of Children and Families must maintain
254 complete medical, dental, and behavioral health encounter
255 information and participate in making such information available
256 to the department or the applicable contracted community-based
257 care lead agency for use in providing comprehensive and
258 coordinated case management. The agency and the department shall
259 establish an interagency agreement to provide guidance for the
260 format, confidentiality, recipient, scope, and method of

261 information to be made available and the deadlines for
262 submission of the data. The scope of information available to
263 the department shall be the data that managed care plans are
264 required to submit to the agency. The agency shall determine the
265 plan's compliance with standards for access to medical, dental,
266 and behavioral health services; the use of medications; and
267 followup on all medically necessary services recommended as a
268 result of early and periodic screening, diagnosis, and
269 treatment.

270 6. If a managed care plan contracts with the state to
271 provide an alternative benefit plan that covers essential health
272 benefits required under federal law, the managed care plan shall
273 not use a benefit design or a manner of implementing a benefit
274 design for providing essential health benefits that
275 discriminates based on an individual's age, expected length of
276 life, race, color, national origin, sex, sexual orientation,
277 present or predicted disability, degree of medical dependency,
278 present or predicted diagnosis, disease or health condition.

279 a. For purposes of this subparagraph, elements of a
280 benefit design and the implementation of a benefit design shall
281 include, but not be limited to, consideration of the categories
282 of benefits included, the specific exclusion of named therapies
283 or conditions, the manner in which coverage decisions are made,
284 differential reimbursement rates or cost sharing for covered
285 benefits, clinical prerequisites or heightened administrative
286 requirements based on the patient's disease, disability, quality

287 or expected length of life, incentive programs, and the
288 burdensomeness or delay of an applicable exceptions process.

289 b. A managed care plan's use of medical management
290 techniques whose effect is a coverage or exception denial for a
291 treatment ordered by a physician, and that apply only to
292 specified diseases or conditions, or to subsets of patients or
293 subscribers, is not considered reasonable and is not consistent
294 with the requirements of this section unless the medical
295 management techniques are:

296 (I) Based on accepted best medical practices for treating
297 such disease, condition, or category of patients.

298 (II) Published in peer-reviewed medical journals or
299 standards of care adopted by medical specialty societies.

300 7.a. The agency shall issue on the agency website an
301 annual report evaluating the process the agency uses to assess
302 the extent to which a managed care plan that covers essential
303 health benefits employs discriminatory practices. Each report
304 shall explain how, if discriminatory practices are identified by
305 the evaluation, such discrimination is addressed by the state
306 and what steps the agency will use to prevent discriminatory
307 practices in the future.

308 b. The first annual report shall evaluate specific steps
309 the state has taken to identify a benefit design or a manner of
310 implementing a benefit design for providing essential health
311 benefits that discriminates, based on criteria including an
312 individual's age, expected length of life, race, color, national

313 origin, gender, sexual orientation, present or predicted
314 disability, degree of medical dependency, present or predicted
315 diagnosis, disease or health condition. The first annual report
316 shall assess the types of plan benefit designs submitted to the
317 state and additional efforts that may be taken to ensure a
318 managed care plan covering essential health benefits does not
319 impermissibly impose clinical prerequisites by limiting care
320 available to those who are sicker, or who have a shorter life
321 expectancy, including consideration of benefit design features
322 such as the categories of benefits included, specific exclusion
323 of named therapies or conditions, the manner in which coverage
324 decisions are made, differential reimbursement rates or cost
325 sharing for covered benefits, clinical prerequisites or
326 heightened administrative requirements based on the patient's
327 disease, disability, quality or expected length of life,
328 incentive programs, and the burdensomeness or delay of an
329 applicable exceptions process. To the extent that discriminatory
330 practices are identified in existing plans the report shall
331 identify such practices in detail and shall identify the steps
332 the agency will take to prevent such discriminatory practices.

333 c. Each subsequent annual report shall detail and evaluate
334 the evolution of the state assessment process and the extent to
335 which discriminatory practices have been identified, mitigated
336 and prevented.

337 Section 3. Section 627.6466, Florida Statutes, is created
338 to read:

339 627.6466 Fail-first protocols.—When medications for the
340 treatment of a medical condition are restricted for use by an
341 insurer through a step-therapy or fail-first protocol, the
342 prescribing physician shall have access to a clear and
343 convenient process to request an override of such restriction
344 from the insurer. The insurer shall grant an override of the
345 protocol within 24 hours under the following circumstances:

346 (1) The prescribing provider recommends, based on sound
347 clinical evidence, that the preferred treatment required under
348 step-therapy or fail-first protocol has been ineffective in the
349 treatment of the insured's disease or medical condition; or

350 (2) Based on sound clinical evidence or medical and
351 scientific evidence, the prescribing provider believes that the
352 preferred treatment required under the step-therapy or fail-
353 first protocol:

354 (a) Is expected or is likely to be ineffective given the
355 known relevant physical or mental characteristics and medical
356 history of the insured and the known characteristics of the drug
357 regimen; or

358 (b) Will cause or will likely cause an adverse reaction or
359 other physical harm to the insured.

360
361 If the prescribing provider allows the insured to enter the
362 step-therapy or fail-first protocol recommended by the health
363 insurer, the duration of the step-therapy or fail-first protocol
364 may not exceed a period deemed appropriate by the provider. If

365 prescribing provider deems the treatment clinically ineffective,
366 the insured is entitled to receive the recommended course of
367 therapy without requiring the prescribing provider to seek
368 approval for an override of the step-therapy or fail-first
369 protocol.

370 Section 4. Section 627.64996, Florida Statutes, is created
371 to read:

372 627.64996 Health insurer accountability.—The Office of
373 Insurance Regulation may on its own initiative or on receipt of
374 a request or complaint hold a public hearing to consider in
375 light of the facts, allegations, and defenses whether it is
376 reasonable to conclude that the provisions of this section are
377 met by a health insurer. When issuing, renewing, or revising the
378 scope of any health insurer's certificate of authority, the
379 office may consider the results of such hearings and the
380 insurer's compliance with this section.

381 (1) NONDISCRIMINATION.—A health insurer that provides a
382 contract or policy that covers the essential health benefits
383 shall not use a benefit design or a manner of implementing a
384 benefit design for providing essential health benefits that
385 discriminates based on an individual's age, expected length of
386 life, race, color, national origin, sex, sexual orientation,
387 present or predicted disability, degree of medical dependency,
388 present or predicted diagnosis, disease or health condition.

389 (a) For purposes of this section, elements of a benefit
390 design and the implementation of the benefit design relevant for

391 public hearing shall include, but not be limited to,
392 consideration of the categories of benefits included, the
393 specific exclusion of named therapies or conditions, the manner
394 in which coverage decisions are made, differential reimbursement
395 rates or cost sharing for covered benefits, clinical
396 prerequisites or heightened administrative requirements based on
397 the patient's disease, disability, quality or expected length of
398 life, incentive programs, and the burdensomeness or delay of an
399 applicable exceptions process.

400 (b) A health insurer's use of medical management
401 techniques whose effect is a coverage or exception denial for a
402 treatment ordered by the patient's physician, and that apply
403 only to specified diseases or conditions, or to subsets of
404 patients or subscribers, is not considered reasonable and is not
405 consistent with the requirements of this section unless the
406 medical management techniques are:

407 1. Based on accepted best medical practices for treating
408 such disease, condition, or category of patients.

409 2. Published in peer-reviewed medical journals or
410 standards of care adopted by medical specialty societies.

411 (2) REPORTING REQUIREMENTS.—Consistent with Section 1302
412 of the Patient Protection and Affordable Care Act, (Pub. L. No.
413 111-148), the Office of Insurance Regulation shall issue an
414 annual report, to be published on the Office of Insurance
415 Regulation website, evaluating the process the state has in
416 place to assess the extent to which a health insurer that holds

417 itself out to the residents of the state as offering a contract
418 or policy that covers the essential health benefits employs
419 discriminatory practices.

420 (a) Each report shall detail how, if discriminatory
421 practices are identified by this state evaluation, such
422 discrimination is addressed by the state and intended steps to
423 prevent discriminatory practices in the future.

424 (b) The first annual report shall be issued no later than
425 December 31, 2015, and shall evaluate specific steps the state
426 has taken to identify a benefit design or a manner of
427 implementing a benefit design for providing essential health
428 benefits that discriminates based on criteria including an
429 individual's age, expected length of life, race, color, national
430 origin, sex, sexual orientation, present or predicted
431 disability, degree of medical dependency, present or predicted
432 diagnosis, disease or health condition.

433 (c) The first annual report shall assess the types of plan
434 benefit designs submitted to the state and additional efforts
435 that may be taken to ensure a health insurance contract or
436 policy covering essential health benefits does not impermissibly
437 impose clinical prerequisites by limiting care available to
438 those who are sicker, or who have a shorter life expectancy,
439 including consideration of benefit design features such as the
440 categories of benefits included; specific exclusion of named
441 therapies or conditions; the manner in which coverage decisions
442 are made; differential reimbursement rates or cost sharing for

443 covered benefits; clinical prerequisites or heightened
444 administrative requirements based on the patient's disease,
445 disability, quality, or expected length of life; incentive
446 programs; and the burdensomeness or delay of an applicable
447 exceptions process. To the extent that discriminatory practices
448 are identified in existing policies or contracts during the
449 course of a plan year, the report shall identify such practices
450 in detail and shall identify steps the state is taking to
451 prevent such discriminatory practices from being approved as
452 part of future plan offerings.

453 (d) Each subsequent annual report shall be issued on a
454 yearly basis thereafter, and shall detail and evaluate the
455 evolution of the state assessment process and the extent to
456 which discriminatory practices have been identified, mitigated
457 and prevented.

458 (3) EXCEPTIONS PROCESS.—All health insurers must have an
459 exceptions process in place that provides timely access to
460 medically necessary therapies and covers such drugs during
461 transitions, which may be enforced by the Office of Insurance
462 Regulation.

463 (a) Required coverage of clinically appropriate drugs not
464 on the formulary.

465 1. All health insurers shall establish and maintain a
466 medical exceptions process that allows insureds or their
467 authorized representatives, including the prescribing health
468 care provider, to request and obtain approval of coverage for

469 any clinically appropriate prescription drug when such drug is
470 not covered based on the health insurance contract or policy's
471 formulary; the health insurer is discontinuing coverage of the
472 drug on the health insurance contract or policy's formulary for
473 reasons other than safety or because the prescription drug has
474 been withdrawn from the market by the drug's manufacturer; or
475 such drug would otherwise not be covered until the insured has
476 satisfied a step therapy requirement or would not be covered at
477 the prescribed number of doses.

478 2. For purposes of this subsection, a prescription drug is
479 "clinically appropriate" to treat the insured's disease or
480 medical condition when the health care provider prescribing the
481 drug submits an oral or written statement stating that he or she
482 has determined that the drug is clinically appropriate based on
483 one of the following criteria:

484 a. All of the prescription drugs on any tier of the health
485 insurance policy's formulary for treatment for the same
486 condition would not be as effective for the insured as the
487 requested drug, or would have adverse effects for the insured;

488 b. The number of doses available under a dose restriction
489 for the prescription drug:

490 (I) Has been ineffective in the treatment of the insured's
491 disease or medical condition; or

492 (II) Based on both sound clinical evidence and medical and
493 scientific evidence, the known relevant physical or mental
494 characteristics of the insured, and known characteristics of the

495 drug regimen, is likely to be ineffective or adversely affect
496 the drug's effectiveness or patient compliance; or

497 c. The prescription drug alternative listed on the
498 formulary or required to be used in accordance with step therapy
499 requirements:

500 (I) Has been ineffective in the treatment of the insured's
501 disease or medical condition or, based on both sound clinical
502 evidence and medical and scientific evidence, the known relevant
503 physical or mental characteristics of the insured, and known
504 characteristics of the drug regimen, is likely to be ineffective
505 or adversely affect the drug's effectiveness or patient
506 compliance; or

507 (II) Has caused or, based on sound clinical evidence and
508 medical and scientific evidence, is likely to cause an adverse
509 reaction or other harm to the insured.

510 3. Notwithstanding any other provision of this section,
511 the health insurance contract or policy must provide coverage
512 for at least one month's supply of the prescription drug that is
513 the subject of any request under this subsection for any new
514 insured under the contract or policy to ensure continuity of
515 coverage.

516 (b) A health insurer's established medical exceptions
517 process must require, at a minimum, the following:

518 1. Any request for approval of coverage made verbally or
519 in writing at any time shall be reviewed by appropriate health
520 care professionals, who shall take into account the specific

521 facts and circumstances of the insured's disease or medical
522 condition and whose decisions shall be made using documented
523 review criteria that are based on sound clinical and medical and
524 scientific evidence.

525 2. The health insurer shall make a decision and notify the
526 insured or the insured's authorized representative of the
527 decision as quickly as the insured's medical condition requires,
528 but in no event later than 72 hours after receipt of the
529 request, or for circumstances in which applying the standard
530 procedure may seriously jeopardize the insured's life, health,
531 or ability regain maximum function, no later than 24 hours after
532 receipt of the request.

533 3. Any denial of a request shall be provided in writing to
534 the insured or the insured's authorized representative and to
535 the insured's prescribing health care provider, and shall
536 contain:

537 a. The specific reason or reasons for the denial.

538 b. A reference to the evidence or documentation, including
539 the clinical review criteria, clinical evidence, and medical and
540 scientific evidence considered in reaching the decision.

541 c. A description of the process and procedures for
542 requesting independent review of the denial.

543 4. Any denial of a request shall be subject to independent
544 review if the insured or the insured's authorized representative
545 requests such review verbally or in writing at any time within
546 60 days after receipt of notification of the denial. The

547 independent review entity shall make a decision and notify the
548 insured or the insured's authorized representative of the
549 decision as quickly as the insured's medical condition requires,
550 but in no event later than 72 hours after the receipt of the
551 request for review, or for circumstances in which applying the
552 standard procedure may seriously jeopardize the insured's life,
553 health, or ability regain maximum function, no later than 24
554 hours after receipt of the request for review.

555 5. The health insurer shall provide coverage of the
556 prescription drug during the entire review process, as long as
557 the prescription drug continues to be prescribed for that
558 insured and is considered safe for the treatment of the
559 insured's medical condition, until a final decision is made by
560 the independent review entity.

561 (c) In the case of an exception granted under this section
562 with respect to an individual insured, a health insurer shall
563 not establish a copayment, coinsurance, or other cost-sharing
564 requirement that exceeds the amount or percentage applicable to
565 the formulary tier for preferred brand name drugs.

566 (d) A health insurer shall provide coverage of any drug
567 approved pursuant to the process established under this section
568 to the insured for as long as the prescription drug continues to
569 be prescribed for that insured and is considered safe for the
570 treatment of the insured's medical condition and the insured
571 remains continuously enrolled in the health insurance policy or
572 contract.

573 (e) The Office of Insurance Regulation shall require each
574 health insurer to maintain written or electronic records
575 sufficient to demonstrate compliance with this section as a
576 condition of certification. Each health insurer shall maintain
577 data and upon request, make available to the Office of Insurance
578 Regulation, the following information with respect to medical
579 exceptions requests made under this subsection:

- 580 1. The total number of medical exceptions requests.
581 2. The number of medical exceptions requests approved and
582 denied.
583 3. Any other information the Commissioner may request.

584 (f) A violation of this section may be a basis for any
585 disciplinary action authorized under state law for noncompliance
586 with the requirements for certification.

587 (4) RIGHT TO TREATMENT.—

588 (a) Notwithstanding any provision of state or federal law,
589 no health insurer shall use treatment guidelines, coverage
590 rules, or criteria for treatment authorization that restrict
591 payment for medically appropriate treatment prescribed by a
592 licensed physician and agreed to by a fully informed individual
593 or his or her advance medical directive or medical power of
594 attorney.

595 (b) Refusing coverage for medically necessary treatment to
596 be rendered to an insured based solely on the insured's life
597 expectancy or the fact that the insured is diagnosed with a
598 terminal condition is a violation of this section.

599 (c) Violations of this section by a health insurer, its
600 agents, or its contractors shall be subject to the remedies and
601 penalties available for unfair or deceptive consumer practices.
602 It is an unfair and deceptive practice to sell or provide health
603 insurance where the financial well-being of the insurer is used
604 to establish coverage and payment rules that deprive a dying
605 individual of dignity and respect.

606 Section 5. Section 641.229, Florida Statutes, is created
607 to read:

608 641.229 Health maintenance organization accountability.—
609 The Office of Insurance Regulation may on its own initiative or
610 on receipt of a request or complaint hold a public hearing to
611 consider in light of the facts, allegations, and defenses
612 whether it is reasonable to conclude that the provisions of this
613 section are met by a health maintenance organization. When
614 issuing, renewing, or revising the scope of any health
615 maintenance organization's certificate of authority, the office
616 may consider the results of such hearings and the organization's
617 compliance with this section.

618 (1) NONDISCRIMINATION.—A health maintenance organization
619 that holds itself out to the residents of this state as
620 providing a contract or policy that covers the essential health
621 benefits shall not use a benefit design or a manner of
622 implementing a benefit design for providing essential health
623 benefits that discriminates based on a subscriber's age,
624 expected length of life, race, color, national origin, sex,

625 sexual orientation, present or predicted disability, degree of
626 medical dependency, present or predicted diagnosis, disease or
627 health condition.

628 (a) For purposes of this section, elements of a benefit
629 design and the implementation of the benefit design relevant for
630 public hearing shall include, but not be limited to,
631 consideration of the categories of benefits included, the
632 specific exclusion of named therapies or conditions, the manner
633 in which coverage decisions are made, differential reimbursement
634 rates or cost sharing for covered benefits, clinical
635 prerequisites or heightened administrative requirements based on
636 the subscriber's disease, disability, quality or expected length
637 of life, incentive programs, and the burdensomeness or delay of
638 an applicable exceptions process.

639 (b) A health maintenance organization's use of medical
640 management techniques whose effect is a coverage or exception
641 denial for a treatment ordered by a subscriber's physician, and
642 that apply only to specified diseases or conditions, or to
643 subsets of patients or subscribers, is not considered reasonable
644 and is not consistent with the requirements of this section
645 unless the medical management techniques are:

646 1. Based on accepted best medical practices for treating
647 such disease, condition, or category of patients.

648 2. Published in peer-reviewed medical journals or
649 standards of care adopted by medical specialty societies.

650 (2) REPORTING REQUIREMENTS.—Consistent with section 1302

651 of the Patient Protection and Affordable Care Act, Pub. L. No.
652 111-148, the Office of Insurance Regulation shall issue an
653 annual report, to be published on the Office of Insurance
654 Regulation website, evaluating the process the state uses to
655 assess the extent to which a health maintenance organization
656 that holds itself out to the residents of the state as offering
657 a contract or policy that covers the essential health benefits
658 employs discriminatory practices.

659 (a) Each report shall detail how, if discriminatory
660 practices are identified by a state evaluation, such
661 discrimination is addressed by the state and intended steps to
662 prevent discriminatory practices in the future.

663 (b) The first annual report shall be issued no later than
664 December 31, 2015, and shall evaluate specific steps the state
665 has taken to identify a benefit design or a manner of
666 implementing a benefit design for providing essential health
667 benefits that discriminates based on criteria including a
668 subscriber's age, expected length of life, race, color, national
669 origin, sex, sexual orientation, present or predicted
670 disability, degree of medical dependency, present or predicted
671 diagnosis, disease or health condition.

672 (c) The first annual report shall assess the types of plan
673 benefit designs submitted to the state and additional efforts
674 that may be taken to ensure a health maintenance organization
675 contract or policy covering essential health benefits does not
676 impermissibly impose clinical prerequisites by limiting care

677 available to those who are sicker, or who have a shorter life
678 expectancy, including consideration of benefit design features
679 such as the categories of benefits included; specific exclusion
680 of named therapies or conditions; the manner in which coverage
681 decisions are made; differential reimbursement rates or cost
682 sharing for covered benefits; clinical prerequisites or
683 heightened administrative requirements based on a subscriber's
684 disease, disability, quality, or expected length of life;
685 incentive programs; and the burdensomeness or delay of an
686 applicable exceptions process. To the extent that discriminatory
687 practices are identified in existing policies or contracts
688 during the course of a plan year, the report shall identify such
689 practices in detail and shall identify steps the state is taking
690 to prevent such discriminatory practices from being approved as
691 part of future plan offerings.

692 (d) Each subsequent annual report shall be issued on a
693 yearly basis thereafter, and shall detail and evaluate the
694 evolution of the state assessment process and the extent to
695 which discriminatory practices have been identified, mitigated,
696 and prevented.

697 (3) EXCEPTIONS PROCESS.—All health maintenance
698 organization must have an exceptions process in place that
699 provides timely access to medically necessary therapies and
700 covers such drugs during transitions, which may be enforced by
701 the Office of Insurance Regulation.

702 (a)1. All health maintenance organizations shall establish

703 and maintain a medical exceptions process that allows
 704 subscribers or their authorized representatives, including the
 705 prescribing health care provider, to request and obtain approval
 706 of coverage for any clinically appropriate prescription drug
 707 when such drug is not covered based on the health maintenance
 708 organization's formulary; the health maintenance organization is
 709 discontinuing coverage of the drug on the health maintenance
 710 organization contract or policy's formulary for reasons other
 711 than safety or because the prescription drug has been withdrawn
 712 from the market by the drug's manufacturer; or such drug would
 713 otherwise not be covered until the subscriber has satisfied a
 714 step therapy requirement or would not be covered at the
 715 prescribed number of doses.

716 2. For purposes of this subsection, a prescription drug is
 717 "clinically appropriate" to treat the subscriber's disease or
 718 medical condition when the health care provider prescribing the
 719 drug submits an oral or written statement stating that he or she
 720 has determined that the drug is clinically appropriate based on
 721 one of the following criteria:

722 a. All of the prescription drugs on any tier of the health
 723 maintenance organization's formulary for treatment for the same
 724 condition would not be as effective for the insured as the
 725 requested drug, or would have adverse effects for the insured;

726 b. The number of doses available under a dose restriction
 727 for the prescription drug:

728 (I) Has been ineffective in the treatment of the

729 subscriber's disease or medical condition; or

730 (II) Based on both sound clinical evidence and medical and
 731 scientific evidence, the known relevant physical or mental
 732 characteristics of the subscriber, and known characteristics of
 733 the drug regimen, is likely to be ineffective or adversely
 734 affect the drug's effectiveness or patient compliance; or

735 c. The prescription drug alternative listed on the
 736 formulary or required to be used in accordance with step therapy
 737 requirements:

738 (I) Has been ineffective in the treatment of the
 739 subscriber's disease or medical condition or, based on both
 740 sound clinical evidence and medical and scientific evidence, the
 741 known relevant physical or mental characteristics of the
 742 insured, and known characteristics of the drug regimen, is
 743 likely to be ineffective or adversely affect the drug's
 744 effectiveness or patient compliance; or

745 (II) Has caused or, based on sound clinical evidence and
 746 medical and scientific evidence, is likely to cause an adverse
 747 reaction or other harm to the insured.

748 3. Notwithstanding any other provision of this section,
 749 the health maintenance organization contract or policy must
 750 provide coverage for at least 1 month's supply of the
 751 prescription drug that is the subject of any request under this
 752 subsection for a new subscriber under the contract or policy to
 753 ensure continuity of coverage.

754 (b) A health maintenance organization's established

755 medical exceptions process must require, at a minimum, the
756 following:

757 1. Any request for approval of coverage made verbally or
758 in writing at any time shall be reviewed by appropriate health
759 care professionals, who shall take into account the specific
760 facts and circumstances of the subscriber's disease or medical
761 condition and whose decisions shall be made using documented
762 review criteria that are based on sound clinical and medical and
763 scientific evidence.

764 2. The health maintenance organization shall make a
765 decision and notify the subscriber or the subscriber's
766 authorized representative of the decision as quickly as the
767 subscriber's medical condition requires, but in no event later
768 than 72 hours after receipt of the request, or for circumstances
769 in which applying the standard procedure may seriously
770 jeopardize the subscriber's life, health, or ability regain
771 maximum function, no later than 24 hours after receipt of the
772 request.

773 3. Any denial of a request shall be provided in writing to
774 the subscriber or the subscriber's authorized representative and
775 to the subscriber's prescribing health care provider, and shall
776 contain:

777 a. The specific reason or reasons for the denial.

778 b. A reference to the evidence or documentation, including
779 the clinical review criteria, clinical evidence, and medical and
780 scientific evidence considered in reaching the decision.

781 c. A description of the process and procedures for
782 requesting independent review of the denial.

783 4. Any denial of a request shall be subject to independent
784 review if the subscriber or the subscriber's authorized
785 representative requests such review verbally or in writing at
786 any time within 60 days after receipt of notification of the
787 denial, the independent review entity shall make a decision and
788 notify the subscriber or the subscriber's authorized
789 representative of the decision as quickly as the subscriber's
790 medical condition requires, but no later than 72 hours after the
791 receipt of the request for review, or for circumstances in which
792 applying the standard procedure may seriously jeopardize the
793 subscriber's life, health, or ability regain maximum function,
794 no later than 24 hours after receipt of the request for review.

795 5. The health maintenance organization shall provide
796 coverage of the prescription drug during the entire review
797 process, as long as the prescription drug continues to be
798 prescribed for that subscriber and is considered safe for the
799 treatment of the subscriber's medical condition, until a final
800 decision is made by the independent review entity.

801 (c) In the case of an exception granted under this section
802 with respect to an individual subscriber, a health maintenance
803 organization shall not establish a copayment, coinsurance, or
804 other cost-sharing requirement that exceeds the amount or
805 percentage applicable to the formulary tier for preferred brand
806 name drugs.

807 (d) A health maintenance organization shall provide
 808 coverage of a drug approved pursuant to the process established
 809 under this section to the subscriber for as long as the
 810 prescription drug continues to be prescribed for that subscriber
 811 and is considered safe for the treatment of the subscriber's
 812 medical condition and the subscriber remains continuously
 813 enrolled in the health insurance policy or contract.

814 (e) The Office of Insurance Regulation shall require each
 815 health maintenance organization to maintain written or
 816 electronic records sufficient to demonstrate compliance with
 817 this section as a condition of certification. Each health
 818 maintenance organization shall maintain data and upon request,
 819 make available to the Office of Insurance Regulation, the
 820 following information with respect to medical exceptions
 821 requests made under this subsection:

- 822 1. The total number of medical exceptions requests.
- 823 2. The number of medical exceptions requests approved and
 824 denied.
- 825 3. Any other information the Commissioner may request.

826 (f) A violation of this section may be a basis for any
 827 disciplinary action authorized under state law for non-
 828 compliance with the requirements for certification.

829 (4) RIGHT TO TREATMENT.—

830 (a) Notwithstanding any provision of state or federal law,
 831 no health maintenance organization shall use treatment
 832 guidelines, coverage rules, or criteria for treatment

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833 authorization that restrict payment for medically appropriate
834 treatment prescribed by a licensed physician and agreed to by a
835 fully informed individual or his or her advance medical
836 directive or medical power of attorney.

837 (b) Refusing coverage for medically necessary treatment to
838 be rendered to a subscriber based solely on the subscriber's
839 life expectancy or the fact that the subscriber is diagnosed
840 with a terminal condition is a violation of this section.

841 (c) Violations of this section by a health maintenance
842 organization, its agents, or its contractors shall be subject to
843 the remedies and penalties available for unfair or deceptive
844 consumer practices. It is an unfair and deceptive practice to
845 sell or provide health care coverage where the financial well-
846 being of the insurer is used to establish coverage and payment
847 rules that deprive a dying individual of dignity and respect.

848 Section 6. Section 641.394, Florida Statutes, is created
849 to read:

850 641.394 Fail-first protocols.—When medications for the
851 treatment of a medical condition are restricted for use by a
852 health maintenance organization through a step-therapy or fail-
853 first protocol, the prescribing physician shall have access to a
854 clear and convenient process to request an override of such
855 restriction from the organization. The health maintenance
856 organization shall grant an override of the protocol within 24
857 hours under the following circumstances:

858 (1) The prescribing provider recommends, based on sound

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859 clinical evidence, that the preferred treatment required under
860 step-therapy or fail-first protocol has been ineffective in the
861 treatment of the subscriber's disease or medical condition; or

862 (2) Based on sound clinical evidence or medical and
863 scientific evidence, the prescribing provider believes that the
864 preferred treatment required under the step-therapy or fail-
865 first protocol:

866 (a) Is expected or is likely to be ineffective the known
867 relevant physical or mental characteristics and medical history
868 of the subscriber, and the known characteristics of the drug
869 regimen; or

870 (b) Will cause or will likely cause an adverse reaction or
871 other physical harm to the subscriber.

872
873 If the prescribing provider allows the subscriber to enter the
874 step-therapy or fail-first protocol recommended by the health
875 maintenance organization, the duration of the step-therapy or
876 fail-first protocol may not exceed a period deemed appropriate
877 by the provider. If the prescribing provider deems the treatment
878 clinically ineffective, the subscriber is entitled to receive
879 the recommended course of therapy without requiring the
880 prescribing provider to seek approval for an override of the
881 step-therapy or fail-first protocol.

882 Section 7. Section 627.6165, Florida Statutes, is created
883 to read:

884 627.6165 Civil liability.—The provisions of this part are

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885 cumulative to rights under the general civil and common law, and
886 no action of the department or office shall abrogate such rights
887 to damages or other relief in any court.

888 (1) A person to whom a duty is owed may bring a civil
889 action against a health insurer that issues a policy pursuant to
890 this part or part VII of this chapter if the person suffers
891 damage as a result of the health insurer's failure to provide a
892 covered service when:

893 (a) The health insurer should have provided such service
894 had it acted in good faith toward its insured and with due
895 regard for the interest of the insured.

896 (b) In the independent medical judgment of a treating
897 physician, the service is medically necessary.

898 (2) If a claimant's civil action against a health insurer
899 is successful, the insurer is liable for all of the claimant's
900 damages, or \$500 per violation of a provision of this part or
901 part VII of this chapter, whichever is larger, and is liable for
902 the claimant's costs and attorney fees.

903 Section 8. Section 641.3917, Florida Statutes, is amended
904 to read:

905 641.3917 Civil liability.—The provisions of this part are
906 cumulative to rights under the general civil and common law, and
907 no action of the department or office shall abrogate such rights
908 to damage or other relief in any court.

909 (1) A person to whom a duty is owed may bring a civil
910 action against a health maintenance organization if the person

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911 suffers damage as a result of the health maintenance
912 organization's failure to provide a covered service when:

913 (a) The health maintenance organization should have
914 provided such service had it acted in good faith toward its
915 subscriber and with due regard for the interest of the
916 subscriber.

917 (b) In the independent medical judgment of a contracted
918 treating physician or other physician authorized by the health
919 maintenance organization, the service is medically necessary.

920 (2) If a subscriber's civil action against a health
921 maintenance organization is successful, the health maintenance
922 organization is liable for all of the subscriber's damages, or
923 \$500 per violation of a provision of this part, whichever is
924 larger, and is liable for the subscriber's costs and attorney
925 fees.

926 Section 9. This act shall take effect July 1, 2015.