By Senator Harrell

| | 25-00636-21 2021528 |
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| 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. |
| 71 | |
| 72 | Be It Enacted by the Legislature of the State of Florida: |
| 73 | |
| 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) DEFINITIONSAs 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) "Medical literature" means scientific studies published |
| 90 | in a United States peer-reviewed national professional journal. |
| 91 | <u>(c)</u> "Standard reference compendium" means authoritative |
| 92 | compendia identified by the Secretary of the United States |
| 93 | Department of Health and Human Services and recognized by the |
| 94 | federal Centers for Medicare and Medicaid Services. |
| 95 | (2) COVERAGE FOR TREATMENT OF CANCER |
| 96 | (a) An insurer <u>or a health maintenance organization</u> may not |
| 97 | exclude coverage in any individual or group <u>health</u> insurance |
| 98 | policy or health maintenance contract issued, amended, |
| 99 | delivered, or renewed in this state which covers the treatment |
| 100 | of cancer for any drug prescribed for the treatment of cancer on |
| 101 | the ground that the drug is not approved by the United States |
| 102 | Food and Drug Administration for a particular indication, if |
| 103 | that drug is recognized for treatment of that indication in a |
| 104 | standard reference compendium or recommended in the medical |
| 105 | literature. |
| 106 | (b) Coverage for a drug required by this section also |
| 107 | includes the medically necessary services associated with the |
| 108 | administration of the drug. |
| 109 | (3) COVERAGE FOR TREATMENT OF STAGE 4 METASTATIC CANCER AND |
| 110 | ASSOCIATED CONDITIONS |
| 111 | (a) An insurer or a health maintenance organization may not |
| 112 | require in any individual or group health insurance policy or |
| 113 | health maintenance contract issued, amended, delivered, or |
| 114 | renewed in this state which covers the treatment of stage 4 |
| 115 | metastatic cancer and its associated conditions that, before a |
| 116 | drug prescribed for the treatment is covered, the insured or |

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| 117 | subscriber fail or have previously failed to respond |
| 118 | successfully to a different drug. |
| 119 | (b) Paragraph (a) applies to a drug that is recognized for |
| 120 | the treatment of such stage 4 metastatic cancer or its |
| 121 | associated conditions, as applicable, in a standard reference |
| 122 | compendium or that is recommended in the medical literature. The |
| 123 | insurer or health maintenance organization may not exclude |
| 124 | coverage for such drug on the ground that the drug is not |
| 125 | approved by the United States Food and Drug Administration for |
| 126 | such stage 4 metastatic cancer or its associated conditions, as |
| 127 | applicable. |
| 128 | (4) COVERAGE FOR SERVICES ASSOCIATED WITH DRUG |
| 129 | ADMINISTRATIONCoverage for a drug required by this section |
| 130 | also includes the medically necessary services associated with |
| 131 | the administration of the drug. |
| 132 | (5)(3) APPLICABILITY AND SCOPEThis section may not be |
| 133 | construed to: |
| 134 | (a) Alter any other law with regard to provisions limiting |
| 135 | coverage for drugs that are not approved by the United States |
| 136 | Food and Drug Administration, except for drugs for the treatment |
| 137 | of stage 4 metastatic cancer or its associated conditions. |
| 138 | (b) Require coverage for any drug, except for a drug for |
| 139 | the treatment of stage 4 metastatic cancer or its associated |
| 140 | conditions, if the United States Food and Drug Administration |
| 141 | has determined that the use of the drug is contraindicated. |
| 142 | (c) Require coverage for a drug that is not otherwise |
| 143 | approved for any indication by the United States Food and Drug |
| 144 | Administration, except for a drug for the treatment of stage 4 |
| 145 | metastatic cancer or its associated conditions. |
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| 146 | (d) Affect the determination as to whether particular |
| 147 | levels, dosages, or usage of a medication associated with bone |
| 148 | marrow transplant procedures are covered under an individual or |
| 149 | group health insurance policy or health maintenance organization |
| 150 | contract. |
| 151 | (e) Apply to specified disease or supplemental policies. |
| 152 | <u>(f)</u> (4) Nothing in this section is intended, Expressly or by |
| 153 | implication, to create, impair, alter, limit, modify, enlarge, |
| 154 | abrogate, prohibit, or withdraw any authority to provide |
| 155 | reimbursement for drugs used in the treatment of any other |
| 156 | disease or condition. |
| 157 | Section 2. Section 627.42392, Florida Statutes, is amended |
| 158 | to read: |
| 159 | 627.42392 Prior authorization |
| 160 | (1) As used in this section, the term: |
| 161 | (a) "Health insurer" means an authorized insurer offering |
| 162 | an individual or group health insurance policy that provides |
| 163 | <u>major medical or similar comprehensive coverage</u> health insurance |
| 164 | as defined in s. 624.603, a managed care plan as defined in s. |
| 165 | 409.962(10), or a health maintenance organization as defined in |
| 166 | s. 641.19(12). |
| 167 | (b) "Urgent care situation" has the same meaning as |
| 168 | provided in s. 627.42393(1). |
| 169 | (2) Notwithstanding any other provision of law, effective |
| 170 | January 1, 2017, or six (6) months after the effective date of |
| 171 | the rule adopting the prior authorization form, whichever is |
| 172 | later, a health insurer, or a pharmacy benefits manager on |
| 173 | behalf of the health insurer, which does not provide an |
| 174 | electronic prior authorization process for use by its contracted |

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| 175 | providers, shall only use the prior authorization form that has |
| 176 | been approved by the Financial Services Commission for granting |
| 177 | a prior authorization for a medical procedure, course of |
| 178 | treatment, or prescription drug benefit. Such form may not |
| 179 | exceed two pages in length, excluding any instructions or |
| 180 | guiding documentation, and must include all clinical |
| 181 | documentation necessary for the health insurer to make a |
| 182 | decision. At a minimum, the form must include: |
| 183 | (a) (1) Sufficient patient information to identify the |
| 184 | member, <u>his or her</u> date of birth, full name, and Health Plan ID |
| 185 | number; |
| 186 | (b)(2) The provider's provider name, address, and phone |
| 187 | number; |
| 188 | <u>(c)</u> The medical procedure, course of treatment, or |
| 189 | prescription drug benefit being requested, including the medical |
| 190 | reason therefor, and all services tried and failed; |
| 191 | (d)(4) Any laboratory documentation required; and |
| 192 | <u>(e)</u> An attestation that all information provided is true |
| 193 | and accurate. |
| 194 | |
| 195 | The form, whether in electronic or paper format, must require |
| 196 | only information that is necessary for the determination of |
| 197 | medical necessity of, or coverage for, the requested medical |
| 198 | procedure, course of treatment, or prescription drug benefit. |
| 199 | The commission may adopt rules prescribing such necessary |
| 200 | information. |
| 201 | (3) The Financial Services Commission <u>,</u> in consultation with |
| 202 | the Agency for Health Care Administration <u>,</u> shall adopt by rule |
| 203 | guidelines for all prior authorization forms which ensure the |

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

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

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| 233 | provider. |
| 234 | |
| 235 | This subsection does not apply to the expansion of health care |
| 236 | services coverage. |
| 237 | (7) A health insurer, or a pharmacy benefits manager on |
| 238 | behalf of the health insurer, must authorize or deny a prior |
| 239 | authorization request and notify the patient and the patient's |
| 240 | treating health care provider of the decision within: |
| 241 | (a) Seventy-two hours after receiving a completed prior |
| 242 | authorization form for nonurgent care situations. |
| 243 | (b) Twenty-four hours after receiving a completed prior |
| 244 | authorization form for urgent care situations. |
| 245 | Section 3. Section 627.42393, Florida Statutes, is amended |
| 246 | to read: |
| 247 | 627.42393 Step-therapy protocol restrictions and |
| 248 | exceptions |
| 249 | (1) DEFINITIONSAs used in this section, the term: |
| 250 | (a) "Health coverage plan" means any of the following which |
| 251 | is currently or was previously providing major medical or |
| 252 | similar comprehensive coverage or benefits to the insured: |
| 253 | 1. A health insurer or health maintenance organization. |
| 254 | 2. A plan established or maintained by an individual |
| 255 | employer as provided by the Employee Retirement Income Security |
| 256 | Act of 1974, Pub. L. No. 93-406. |
| 257 | 3. A multiple-employer welfare arrangement as defined in s. |
| 258 | 624.437. |
| 259 | 4. A governmental entity providing a plan of self- |
| 260 | insurance. |
| 261 | (b) "Health insurer" has the same meaning as provided in s. |
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| 262 | 627.42392. |
| 263 | (c) "Preceding prescription drug or medical treatment" |
| 264 | means a prescription drug, medical procedure, or course of |
| 265 | treatment that must be used pursuant to a health insurer's step- |
| 266 | therapy protocol as a condition of coverage under a health |
| 267 | insurance policy to treat an insured's condition. |
| 268 | (d) "Protocol exception" means a determination by a health |
| 269 | insurer that a step-therapy protocol is not medically |
| 270 | appropriate or indicated for treatment of an insured's |
| 271 | condition, and the health insurer authorizes the use of another |
| 272 | medical procedure, course of treatment, or prescription drug |
| 273 | prescribed or recommended by the treating health care provider |
| 274 | for the insured's condition. |
| 275 | (e) "Step-therapy protocol" means a written protocol that |
| 276 | specifies the order in which certain medical procedures, courses |
| 277 | of treatment, or prescription drugs must be used to treat an |
| 278 | insured's condition. |
| 279 | (f) "Urgent care situation" means an injury or condition of |
| 280 | an insured which, if medical care and treatment are not provided |
| 281 | earlier than the time the medical profession generally considers |
| 282 | reasonable for a nonurgent situation, in the opinion of the |
| 283 | insured's treating physician, physician assistant, or advanced |
| 284 | practice registered nurse, would: |
| 285 | 1. Seriously jeopardize the insured's life, health, or |
| 286 | ability to regain maximum function; or |
| 287 | 2. Subject the insured to severe pain that cannot be |
| 288 | adequately managed. |
| 289 | (2) STEP-THERAPY PROTOCOL RESTRICTIONSIn addition to |
| 290 | protocol exceptions granted under subsection (3) and the |
| | |

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| restriction under s. 627.4239(3), a health insurer issuing a |
| major medical individual or group policy may not require a step- |
| therapy protocol under the policy for a covered prescription |
| 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 request. |
| (3) STEP-THERAPY PROTOCOL EXCEPTIONS; REQUIREMENTS AND |
| PROCEDURES |
| (a) A health insurer shall publish on its website and |
| provide to an insured in writing a procedure for the insured and |
| his or her health care provider to request a protocol exception. |
| The procedure must include: |
| 1. The manner in which an insured or health care provider |
| may request a protocol exception. |
| 2. The manner and timeframe in which the health insurer is |
| required to authorize or deny a protocol exception request or to |
| respond to an appeal of the health insurer's authorization or |
| denial of a request. |
| 3. The conditions under which the protocol exception |
| request must be granted. |
| (b)1. A health insurer must authorize or deny a protocol |
| exception request or respond to an appeal of a health insurer's |
| authorization or denial of a request within: |
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| 320 | a. Seventy-two hours after receiving a completed prior |
| 321 | authorization form for nonurgent care situations. |
| 322 | b. Twenty-four hours after receiving a completed prior |
| 323 | authorization form for urgent care situations. |
| 324 | 2. An authorization of the request must specify the |
| 325 | approved medical procedure, course of treatment, or prescription |
| 326 | drug benefits. |
| 327 | 3. A denial of the request must include a detailed written |
| 328 | explanation of the reason for the denial, the clinical rationale |
| 329 | that supports the denial, and the procedure for appealing the |
| 330 | health insurer's determination. |
| 331 | (c) A health insurer must grant a protocol exception |
| 332 | request if any of the following applies: |
| 333 | 1. A preceding prescription drug or medical treatment is |
| 334 | contraindicated or will likely cause an adverse reaction or |
| 335 | physical or mental harm to the insured. |
| 336 | 2. A preceding prescription drug or medical treatment is |
| 337 | expected to be ineffective based on the insured's medical |
| 338 | history and the clinical evidence of the characteristics of the |
| 339 | preceding prescription drug or medical treatment. |
| 340 | 3. The insured has previously received a preceding |
| 341 | prescription drug or medical treatment that is in the same |
| 342 | pharmacologic class or has the same mechanism of action and such |
| 343 | drug or treatment lacked efficacy or effectiveness or adversely |
| 344 | affected the insured. |
| 345 | 4. A preceding prescription drug or medical treatment is |
| 346 | not in the insured's best interest because his or her use of the |
| 347 | drug or treatment is expected to: |
| 348 | a. Cause a significant barrier to the insured's adherence |
| | |

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| 349 | to or compliance with his or her plan of care; |
| 350 | b. Worsen the insured's medical condition that exists |
| 351 | simultaneously with, but independently of, the condition under |
| 352 | treatment; or |
| 353 | c. Decrease the insured's ability to achieve or maintain |
| 354 | his or her ability to perform daily activities. |
| 355 | 5. A preceding prescription drug is an opioid and the |
| 356 | protocol exception request is for a nonopioid prescription drug |
| 357 | or treatment with a likelihood of similar or better results. |
| 358 | (d) A health insurer may request a copy of relevant |
| 359 | documentation from an insured's medical record in support of a |
| 360 | protocol exception request |
| 361 | (2) As used in this section, the term "health coverage |
| 362 | plan" means any of the following which is currently or was |
| 363 | previously providing major medical or similar comprehensive |
| 364 | coverage or benefits to the insured: |
| 365 | (a) A health insurer or health maintenance organization. |
| 366 | (b) A plan established or maintained by an individual |
| 367 | employer as provided by the Employee Retirement Income Security |
| 368 | Act of 1974, Pub. L. No. 93-406. |
| 369 | (c) A multiple-employer welfare arrangement as defined in |
| 370 | s. 624.437. |
| 371 | (d) A governmental entity providing a plan of self- |
| 372 | insurance. |
| 373 | (4) (3) CONSTRUCTION.—This section does not require a health |
| 374 | insurer to add a drug to its prescription drug formulary or to |
| 375 | cover a prescription drug that the insurer does not otherwise |
| 376 | cover. |
| 377 | Section 4. Subsection (11) of section 627.6131, Florida |
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| 378 | Statutes, is amended, and subsection (20) is added to that |
| 379 | section, to read: |
| 380 | 627.6131 Payment of claims |
| 381 | (11) A health insurer may not retroactively deny a claim |
| 382 | because of insured ineligibility <u>:</u> |
| 383 | (a) More than 1 year after the date of payment of the |
| 384 | claim <u>; or</u> |
| 385 | (b) At any time, if the health insurer verified the |
| 386 | insured's eligibility at the time of treatment or provided an |
| 387 | authorization number. |
| 388 | (20) A health insurer may not impose an additional prior |
| 389 | authorization requirement with respect to a surgical or |
| 390 | otherwise invasive procedure, or any item furnished as part of |
| 391 | the surgical or invasive procedure, if the procedure or item is |
| 392 | furnished during the perioperative period of another procedure |
| 393 | for which prior authorization was granted by the health insurer. |
| 394 | Section 5. Subsection (46) of section 641.31, Florida |
| 395 | Statutes, is amended to read: |
| 396 | 641.31 Health maintenance contracts |
| 397 | (46)(a) <i>Definitions.</i> —As used in this subsection, the term: |
| 398 | 1. "Health coverage plan" means any of the following which |
| 399 | is currently or was previously providing major medical or |
| 400 | similar comprehensive coverage or benefits to the subscriber: |
| 401 | a. A health insurer or health maintenance organization. |
| 402 | b. A plan established or maintained by an individual |
| 403 | employer as provided by the Employee Retirement Income Security |
| 404 | Act of 1974, Pub. L. No. 93-406. |
| 405 | c. A multiple-employer welfare arrangement as defined in s. |
| 406 | <u>624.437.</u> |
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| 407 | d. A governmental entity providing a plan of self- |
| 408 | insurance. |
| 409 | 2. "Preceding prescription drug or medical treatment" means |
| 410 | a prescription drug, medical procedure, or course of treatment |
| 411 | that must be used pursuant to a health maintenance |
| 412 | organization's step-therapy protocol as a condition of coverage |
| 413 | under a health maintenance contract to treat a subscriber's |
| 414 | condition. |
| 415 | 3. "Protocol exception" means a determination by a health |
| 416 | maintenance organization that a step-therapy protocol is not |
| 417 | medically appropriate or indicated for treatment of a |
| 418 | subscriber's condition, and the health maintenance organization |
| 419 | authorizes the use of another medical procedure, course of |
| 420 | treatment, or prescription drug prescribed or recommended by the |
| 421 | treating health care provider for the subscriber's condition. |
| 422 | 4. "Step-therapy protocol" means a written protocol that |
| 423 | specifies the order in which certain medical procedures, courses |
| 424 | of treatment, or prescription drugs must be used to treat a |
| 425 | subscriber's condition. |
| 426 | 5. "Urgent care situation" means an injury or condition of |
| 427 | a subscriber which, if medical care and treatment are not |
| 428 | provided earlier than the time the medical profession generally |
| 429 | considers reasonable for a nonurgent situation, in the opinion |
| 430 | of the subscriber's treating physician, physician assistant, or |
| 431 | advanced practice registered nurse, would: |
| 432 | a. Seriously jeopardize the subscriber's life, health, or |
| 433 | ability to regain maximum function; or |
| 434 | b. Subject the subscriber to severe pain that cannot be |
| 435 | adequately managed. |

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| 436 | (b) Step-therapy protocol restrictionsIn addition to |
| 437 | protocol exceptions granted under paragraph (c) and the |
| 438 | restriction under s. 627.4239(3), a health maintenance |
| 439 | organization issuing major medical coverage through an |
| 440 | individual or group contract may not require a step-therapy |
| 441 | protocol under the contract for a covered prescription drug |
| 442 | requested by a subscriber if: |
| 443 | 1. The subscriber has previously been approved to receive |
| 444 | the prescription drug through the completion of a step-therapy |
| 445 | protocol required by a separate health coverage plan; and |
| 446 | 2. The subscriber provides documentation originating from |
| 447 | the health coverage plan that approved the prescription drug as |
| 448 | described in subparagraph 1. indicating that the health coverage |
| 449 | plan paid for the drug on the subscriber's behalf during the 90 |
| 450 | days immediately before the request. |
| 451 | (c) Step-therapy protocol exceptions; requirements and |
| 452 | procedures |
| 453 | 1. A health maintenance organization shall publish on its |
| 454 | website and provide to a subscriber in writing a procedure for |
| 455 | the subscriber and his or her health care provider to request a |
| 456 | protocol exception. The procedure must include: |
| 457 | a. The manner in which a subscriber or health care provider |
| 458 | may request a protocol exception. |
| 459 | b. The manner and timeframe in which the health maintenance |
| 460 | organization is required to authorize or deny a protocol |
| 461 | exception request or to respond to an appeal of the health |
| 462 | maintenance organization's authorization or denial of a request. |
| 463 | c. The conditions under which the protocol exception |
| 464 | request must be granted. |
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| 465 | 2.a. A health maintenance organization must authorize or |
| 466 | deny a protocol exception request or respond to an appeal of a |
| 467 | health maintenance organization's authorization or denial of a |
| 468 | request within: |
| 469 | (I) Seventy-two hours after receiving a completed prior |
| 470 | authorization form for nonurgent care situations. |
| 471 | (II) Twenty-four hours after receiving a completed prior |
| 472 | authorization form for urgent care situations. |
| 473 | b. An authorization of the request must specify the |
| 474 | approved medical procedure, course of treatment, or prescription |
| 475 | drug benefits. |
| 476 | c. A denial of the request must include a detailed written |
| 477 | explanation of the reason for the denial, the clinical rationale |
| 478 | that supports the denial, and the procedure for appealing the |
| 479 | health maintenance organization's determination. |
| 480 | 3. A health maintenance organization must grant a protocol |
| 481 | exception request if any of the following applies: |
| 482 | a. A preceding prescription drug or medical treatment is |
| 483 | contraindicated or will likely cause an adverse reaction or |
| 484 | physical or mental harm to the subscriber. |
| 485 | b. A preceding prescription drug or medical treatment is |
| 486 | expected to be ineffective based on the subscriber's medical |
| 487 | history and the clinical evidence of the characteristics of the |
| 488 | preceding prescription drug or medical treatment. |
| 489 | c. The subscriber has previously received a preceding |
| 490 | prescription drug or medical treatment that is in the same |
| 491 | pharmacologic class or has the same mechanism of action and such |
| 492 | drug or treatment lacked efficacy or effectiveness or adversely |
| 493 | affected the subscriber. |

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| 494 | d. A preceding prescription drug or medical treatment is |
| 495 | not in the subscriber's best interest because his or her use of |
| 496 | the drug or treatment is expected to: |
| 497 | (I) Cause a significant barrier to the subscriber's |
| 498 | adherence to or compliance with his or her plan of care; |
| 499 | (II) Worsen the subscriber's medical condition that exists |
| 500 | simultaneously with, but independently of, the condition under |
| 501 | treatment; or |
| 502 | (III) Decrease the subscriber's ability to achieve or |
| 503 | maintain his or her ability to perform daily activities. |
| 504 | e. A preceding prescription drug is an opioid and the |
| 505 | protocol exception request is for a nonopioid prescription drug |
| 506 | or treatment with a likelihood of similar or better results. |
| 507 | 4. A health maintenance organization may request a copy of |
| 508 | relevant documentation from a subscriber's medical record in |
| 509 | support of a protocol exception request |
| 510 | (b) As used in this subsection, the term "health coverage |
| 511 | plan" means any of the following which previously provided or is |
| 512 | currently providing major medical or similar comprehensive |
| 513 | coverage or benefits to the subscriber: |
| 514 | 1. A health insurer or health maintenance organization; |
| 515 | 2. A plan established or maintained by an individual |
| 516 | employer as provided by the Employee Retirement Income Security |
| 517 | Act of 1974, Pub. L. No. 93-406; |
| 518 | 3. A multiple-employer welfare arrangement as defined in s. |
| 519 | 624.437; or |
| 520 | 4. A governmental entity providing a plan of self- |
| 521 | insurance. |
| 522 | (d) (c) <u>Construction.</u> This subsection does not require a |
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| 523 | health maintenance organization to add a drug to its |
| 524 | prescription drug formulary or to cover a prescription drug that |
| 525 | the health maintenance organization does not otherwise cover. |
| 526 | Section 6. Subsection (10) of section 641.3155, Florida |
| 527 | Statutes, is amended to read: |
| 528 | 641.3155 Prompt payment of claims |
| 529 | (10) A health maintenance organization may not |
| 530 | retroactively deny a claim because of subscriber ineligibility: |
| 531 | (a) More than 1 year after the date of payment of the |
| 532 | claim <u>; or</u> |
| 533 | (b) At any time, if the health maintenance organization |
| 534 | verified the subscriber's eligibility at the time of treatment |
| 535 | or provided an authorization number. |
| 536 | Section 7. Subsection (4) is added to section 641.3156, |
| 537 | Florida Statutes, to read: |
| 538 | 641.3156 Treatment authorization; payment of claims |
| 539 | (4) A health maintenance organization may not impose an |
| 540 | additional prior authorization requirement with respect to a |
| 541 | surgical or otherwise invasive procedure, or any item furnished |
| 542 | as part of the surgical or invasive procedure, if the procedure |
| 543 | or item is furnished during the perioperative period of another |
| 544 | procedure for which prior authorization was granted by the |
| 545 | health maintenance organization. |
| 546 | Section 8. This act shall take effect January 1, 2022. |
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CODING: Words stricken are deletions; words underlined are additions.

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