**By** Senator Harrell

25-00636-21 2021528__

A bill to be entitled

An act relating to health insurance prior authorization; amending s. 627.4239, F.S.; defining the terms "associated condition" and "health care provider"; prohibiting health maintenance organizations from excluding coverage for certain cancer treatment drugs; prohibiting health insurers and health maintenance organizations from requiring, before providing prescription drug coverage for the treatment of stage 4 metastatic cancer and associated conditions, that treatment has failed with a different drug; providing applicability; prohibiting insurers and health maintenance organizations from excluding coverage for certain drugs on certain grounds; revising construction; amending s. 627.42392, F.S.; revising the definition of the term "health insurer"; defining the term "urgent care situation"; specifying a requirement for the prior authorization form adopted by the Financial Services Commission by rule; authorizing the commission to adopt certain rules; specifying requirements for, and restrictions on, health insurers and pharmacy benefits managers relating to prior authorization information, requirements, restrictions, and changes; providing applicability; specifying timeframes in which prior authorization requests must be authorized or denied and the patient and the patient's provider must be notified; amending s. 627.42393, F.S.; defining terms; requiring health insurers to provide and disclose

procedures for insureds to request exceptions to step-therapy protocols; specifying requirements for such procedures and disclosures; requiring health insurers to authorize or deny protocol exception requests and respond to certain appeals within specified timeframes; specifying required information in authorizations and denials of such requests; requiring health insurers to grant a protocol exception request under specified circumstances; authorizing health insurers to request certain documentation; conforming provisions to changes made by the act; amending s. 627.6131, F.S.; prohibiting health insurers, under certain circumstances, from retroactively denying a claim at any time because of insured ineligibility; prohibiting health insurers from imposing an additional prior authorization requirement with respect to certain surgical or invasive procedures or certain items; amending s. 641.31, F.S.; defining terms; requiring health maintenance organizations to provide and disclose procedures for subscribers to request exceptions to step-therapy protocols; specifying requirements for such procedures and disclosures; requiring health maintenance organizations to authorize or deny protocol exception requests and respond to certain appeals within specified timeframes; specifying required information in authorizations and denials of such requests; requiring health maintenance organizations to grant a protocol exception request under specified

circumstances; authorizing health maintenance organizations to request certain documentation; conforming provisions to changes made by the act; amending s. 641.3155, F.S.; prohibiting health maintenance organizations, under certain circumstances, from retroactively denying a claim at any time because of subscriber ineligibility; amending s. 641.3156, F.S.; prohibiting health maintenance organizations from imposing an additional prior authorization requirement with respect to certain surgical or invasive procedures or certain items; providing an effective date.

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

Section 1. Section 627.4239, Florida Statutes, is amended to read:

627.4239 Coverage for use of drugs in treatment of cancer.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Associated condition" means a symptom or side effect that:

1. Is associated with a particular cancer at a particular stage or with the treatment of that cancer; and

2. In the judgment of a health care provider, will further jeopardize the health of a patient if left untreated. As used in this subparagraph, the term "health care provider" means a physician licensed under chapter 458, chapter 459, or chapter 461, a physician assistant licensed under chapter 458 or chapter 459, an advanced practice registered nurse licensed under

chapter 464, or a dentist licensed under chapter 466.

(b) "Medical literature" means scientific studies published in a United States peer-reviewed national professional journal.

(c) ~~(b)~~ "Standard reference compendium" means authoritative compendia identified by the Secretary of the United States Department of Health and Human Services and recognized by the federal Centers for Medicare and Medicaid Services.

(2) COVERAGE FOR TREATMENT OF CANCER.—

~~(a)~~ An insurer or a health maintenance organization may not exclude coverage in any individual or group health insurance policy or health maintenance contract issued, amended, delivered, or renewed in this state which covers the treatment of cancer for any drug prescribed for the treatment of cancer on the ground that the drug is not approved by the United States Food and Drug Administration for a particular indication, if that drug is recognized for treatment of that indication in a standard reference compendium or recommended in the medical literature.

~~(b) Coverage for a drug required by this section also includes the medically necessary services associated with the administration of the drug.~~

(3) COVERAGE FOR TREATMENT OF STAGE 4 METASTATIC CANCER AND ASSOCIATED CONDITIONS.—

(a) An insurer or a health maintenance organization may not require in any individual or group health insurance policy or health maintenance contract issued, amended, delivered, or renewed in this state which covers the treatment of stage 4 metastatic cancer and its associated conditions that, before a drug prescribed for the treatment is covered, the insured or

subscriber fail or have previously failed to respond successfully to a different drug.

(b) Paragraph (a) applies to a drug that is recognized for the treatment of such stage 4 metastatic cancer or its associated conditions, as applicable, in a standard reference compendium or that is recommended in the medical literature. The insurer or health maintenance organization may not exclude coverage for such drug on the ground that the drug is not approved by the United States Food and Drug Administration for such stage 4 metastatic cancer or its associated conditions, as applicable.

(4) COVERAGE FOR SERVICES ASSOCIATED WITH DRUG ADMINISTRATION.—Coverage for a drug required by this section also includes the medically necessary services associated with the administration of the drug.

(5)~~(3)~~ APPLICABILITY AND SCOPE.—This section may not be construed to:

(a) Alter any other law with regard to provisions limiting coverage for drugs that are not approved by the United States Food and Drug Administration, except for drugs for the treatment of stage 4 metastatic cancer or its associated conditions.

(b) Require coverage for any drug, except for a drug for the treatment of stage 4 metastatic cancer or its associated conditions, if the United States Food and Drug Administration has determined that the use of the drug is contraindicated.

(c) Require coverage for a drug that is not otherwise approved for any indication by the United States Food and Drug Administration, except for a drug for the treatment of stage 4 metastatic cancer or its associated conditions.

(d) Affect the determination as to whether particular levels, dosages, or usage of a medication associated with bone marrow transplant procedures are covered under an individual or group health insurance policy or health maintenance organization contract.

(e) Apply to specified disease or supplemental policies.

(f) ~~(4) Nothing in this section is intended,~~ Expressly or by implication, ~~to~~ create, impair, alter, limit, modify, enlarge, abrogate, prohibit, or withdraw any authority to provide reimbursement for drugs used in the treatment of any other disease or condition.

Section 2. Section 627.42392, Florida Statutes, is amended to read:

627.42392 Prior authorization.—

(1) As used in this section, the term:

(a) "Health insurer" means an authorized insurer offering an individual or group health insurance policy that provides major medical or similar comprehensive coverage ~~health insurance as defined in s. 624.603~~, a managed care plan as defined in s. 409.962(10), or a health maintenance organization as defined in s. 641.19(12).

(b) "Urgent care situation" has the same meaning as provided in s. 627.42393(1).

(2) Notwithstanding any other ~~provision of~~ law, effective January 1, 2017, or six (6) months after the effective date of the rule adopting the prior authorization form, whichever is later, a health insurer, or a pharmacy benefits manager on behalf of the health insurer, which does not provide an electronic prior authorization process for use by its contracted

providers, shall only use the prior authorization form that has been approved by the Financial Services Commission for granting a prior authorization for a medical procedure, course of treatment, or prescription drug benefit. Such form may not exceed two pages in length, excluding any instructions or guiding documentation, and must include all clinical documentation necessary for the health insurer to make a decision. At a minimum, the form must include:

(a) ~~(1)~~ Sufficient patient information to identify the member, his or her date of birth, full name, and Health Plan ID number;

(b) ~~(2)~~ The provider's ~~provider~~ name, address, and phone number;

(c) ~~(3)~~ The medical procedure, course of treatment, or prescription drug benefit being requested, including the medical reason therefor, and all services tried and failed;

(d) ~~(4)~~ Any laboratory documentation required; and

(e) ~~(5)~~ An attestation that all information provided is true and accurate.

The form, whether in electronic or paper format, must require only information that is necessary for the determination of medical necessity of, or coverage for, the requested medical procedure, course of treatment, or prescription drug benefit. The commission may adopt rules prescribing such necessary information.

(3) The Financial Services Commission, in consultation with the Agency for Health Care Administration, shall adopt by rule guidelines for all prior authorization forms which ensure the

general uniformity of such forms.

(4) Electronic prior authorization approvals do not preclude benefit verification or medical review by the insurer under either the medical or pharmacy benefits.

(5) A health insurer, or a pharmacy benefits manager on behalf of the health insurer, shall provide upon request the following information in writing or in an electronic format and publish it on a publicly accessible website:

(a) Detailed descriptions in clear, easily understandable language of the requirements for, and restrictions on, obtaining prior authorization for coverage of a medical procedure, course of treatment, or prescription drug. Clinical criteria must be described in language a health care provider can easily understand.

(b) Prior authorization forms.

(6) A health insurer, or a pharmacy benefits manager on behalf of the health insurer, may not implement any new requirements or restrictions or make changes to existing requirements or restrictions on obtaining prior authorization unless:

(a) The changes have been available on a publicly accessible website for at least 60 days before they are implemented; and

(b) Policyholders and health care providers who are affected by the new requirements and restrictions or changes to the requirements and restrictions are provided with a written notice of the changes at least 60 days before they are implemented. Such notice may be delivered electronically or by other means as agreed to by the insured or the health care

provider.

This subsection does not apply to the expansion of health care services coverage.

(7) A health insurer, or a pharmacy benefits manager on behalf of the health insurer, must authorize or deny a prior authorization request and notify the patient and the patient's treating health care provider of the decision within:

(a) Seventy-two hours after receiving a completed prior authorization form for nonurgent care situations.

(b) Twenty-four hours after receiving a completed prior authorization form for urgent care situations.

Section 3. Section 627.42393, Florida Statutes, is amended to read:

627.42393 Step-therapy protocol restrictions and exceptions.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Health coverage plan" means any of the following which is currently or was previously providing major medical or similar comprehensive coverage or benefits to the insured:

1. A health insurer or health maintenance organization.

2. A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406.

3. A multiple-employer welfare arrangement as defined in s. 624.437.

4. A governmental entity providing a plan of self-insurance.

(b) "Health insurer" has the same meaning as provided in s.

627.42392.

(c) "Preceding prescription drug or medical treatment" means a prescription drug, medical procedure, or course of treatment that must be used pursuant to a health insurer's step-therapy protocol as a condition of coverage under a health insurance policy to treat an insured's condition.

(d) "Protocol exception" means a determination by a health insurer that a step-therapy protocol is not medically appropriate or indicated for treatment of an insured's condition, and the health insurer authorizes the use of another medical procedure, course of treatment, or prescription drug prescribed or recommended by the treating health care provider for the insured's condition.

(e) "Step-therapy protocol" means a written protocol that specifies the order in which certain medical procedures, courses of treatment, or prescription drugs must be used to treat an insured's condition.

(f) "Urgent care situation" means an injury or condition of an insured which, if medical care and treatment are not provided earlier than the time the medical profession generally considers reasonable for a nonurgent situation, in the opinion of the insured's treating physician, physician assistant, or advanced practice registered nurse, would:

1. Seriously jeopardize the insured's life, health, or ability to regain maximum function; or

2. Subject the insured to severe pain that cannot be adequately managed.

(2) STEP-THERAPY PROTOCOL RESTRICTIONS.—In addition to protocol exceptions granted under subsection (3) and the

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:

a. Seventy-two hours after receiving a completed prior authorization form for nonurgent care situations.

b. Twenty-four hours after receiving a completed prior authorization form for urgent care situations.

2. An authorization of the request must specify the approved medical procedure, course of treatment, or prescription drug benefits.

3. A denial of the request must include a detailed written explanation of the reason for the denial, the clinical rationale that supports the denial, and the procedure for appealing the health insurer's determination.

(c) A health insurer must grant a protocol exception request if any of the following applies:

1. A preceding prescription drug or medical treatment is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.

2. A preceding prescription drug or medical treatment is expected to be ineffective based on the insured's medical history and the clinical evidence of the characteristics of the preceding prescription drug or medical treatment.

3. The insured has previously received a preceding prescription drug or medical treatment that is in the same pharmacologic class or has the same mechanism of action and such drug or treatment lacked efficacy or effectiveness or adversely affected the insured.

4. A preceding prescription drug or medical treatment is not in the insured's best interest because his or her use of the drug or treatment is expected to:

a. Cause a significant barrier to the insured's adherence

to or compliance with his or her plan of care;

b. Worsen the insured's medical condition that exists simultaneously with, but independently of, the condition under treatment; or

c. Decrease the insured's ability to achieve or maintain his or her ability to perform daily activities.

5. A preceding prescription drug is an opioid and the protocol exception request is for a nonopioid prescription drug or treatment with a likelihood of similar or better results.

(d) A health insurer may request a copy of relevant documentation from an insured's medical record in support of a protocol exception request

~~(2) As used in this section, the term "health coverage plan" means any of the following which is currently or was previously providing major medical or similar comprehensive coverage or benefits to the insured:~~

~~(a) A health insurer or health maintenance organization.~~

~~(b) A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406.~~

~~(c) A multiple-employer welfare arrangement as defined in s. 624.437.~~

~~(d) A governmental entity providing a plan of self-insurance~~.

(4) ~~(3)~~ CONSTRUCTION.—This section does not require a health insurer to add a drug to its prescription drug formulary or to cover a prescription drug that the insurer does not otherwise cover.

Section 4. Subsection (11) of section 627.6131, Florida

Statutes, is amended, and subsection (20) is added to that section, to read:

627.6131 Payment of claims.—

(11) A health insurer may not retroactively deny a claim because of insured ineligibility:

(a) More than 1 year after the date of payment of the claim; or

(b) At any time, if the health insurer verified the insured's eligibility at the time of treatment or provided an authorization number.

(20) A health insurer may not impose an additional prior authorization requirement with respect to a surgical or otherwise invasive procedure, or any item furnished as part of the surgical or invasive procedure, if the procedure or item is furnished during the perioperative period of another procedure for which prior authorization was granted by the health insurer.

Section 5. Subsection (46) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(46)(a) *Definitions.*—As used in this subsection, the term:

1. "Health coverage plan" means any of the following which is currently or was previously providing major medical or similar comprehensive coverage or benefits to the subscriber:

a. A health insurer or health maintenance organization.

b. A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406.

c. A multiple-employer welfare arrangement as defined in s. 624.437.

d. A governmental entity providing a plan of self-insurance.

2. "Preceding prescription drug or medical treatment" means a prescription drug, medical procedure, or course of treatment that must be used pursuant to a health maintenance organization's step-therapy protocol as a condition of coverage under a health maintenance contract to treat a subscriber's condition.

3. "Protocol exception" means a determination by a health maintenance organization that a step-therapy protocol is not medically appropriate or indicated for treatment of a subscriber's condition, and the health maintenance organization authorizes the use of another medical procedure, course of treatment, or prescription drug prescribed or recommended by the treating health care provider for the subscriber's condition.

4. "Step-therapy protocol" means a written protocol that specifies the order in which certain medical procedures, courses of treatment, or prescription drugs must be used to treat a subscriber's condition.

5. "Urgent care situation" means an injury or condition of a subscriber which, if medical care and treatment are not provided earlier than the time the medical profession generally considers reasonable for a nonurgent situation, in the opinion of the subscriber's treating physician, physician assistant, or advanced practice registered nurse, would:

a. Seriously jeopardize the subscriber's life, health, or ability to regain maximum function; or

b. Subject the subscriber to severe pain that cannot be 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.

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

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

a. The manner in which a subscriber or health care provider may request a protocol exception.

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 request must be granted.

2.a. A health maintenance organization must authorize or deny a protocol exception request or respond to an appeal of a health maintenance organization's authorization or denial of a request within:

(I) Seventy-two hours after receiving a completed prior authorization form for nonurgent care situations.

(II) Twenty-four hours after receiving a completed prior authorization form for urgent care situations.

b. An authorization of the request must specify the approved medical procedure, course of treatment, or prescription drug benefits.

c. A denial of the request must include a detailed written explanation of the reason for the denial, the clinical rationale that supports the denial, and the procedure for appealing the health maintenance organization's determination.

3. A health maintenance organization must grant a protocol exception request if any of the following applies:

a. A preceding prescription drug or medical treatment is contraindicated or will likely cause an adverse reaction or physical or mental harm to the subscriber.

b. A preceding prescription drug or medical treatment is expected to be ineffective based on the subscriber's medical history and the clinical evidence of the characteristics of the preceding prescription drug or medical treatment.

c. The subscriber has previously received a preceding prescription drug or medical treatment that is in the same pharmacologic class or has the same mechanism of action and such drug or treatment lacked efficacy or effectiveness or adversely affected the subscriber.

d. A preceding prescription drug or medical treatment is not in the subscriber's best interest because his or her use of the drug or treatment is expected to:

(I) Cause a significant barrier to the subscriber's adherence to or compliance with his or her plan of care;

(II) Worsen the subscriber's medical condition that exists simultaneously with, but independently of, the condition under treatment; or

(III) Decrease the subscriber's ability to achieve or maintain his or her ability to perform daily activities.

e. A preceding prescription drug is an opioid and the protocol exception request is for a nonopioid prescription drug or treatment with a likelihood of similar or better results.

4. A health maintenance organization may request a copy of relevant documentation from a subscriber's medical record in support of a protocol exception request

~~(b) As used in this subsection, the term "health coverage plan" means any of the following which previously provided or is currently providing major medical or similar comprehensive coverage or benefits to the subscriber:~~

~~1. A health insurer or health maintenance organization;~~

~~2. A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406;~~

~~3. A multiple-employer welfare arrangement as defined in s. 624.437; or~~

~~4. A governmental entity providing a plan of self-insurance~~.

(d) ~~(c)~~ *Construction.*—This subsection does not require a

health maintenance organization to add a drug to its prescription drug formulary or to cover a prescription drug that the health maintenance organization does not otherwise cover.

Section 6. Subsection (10) of section 641.3155, Florida Statutes, is amended to read:

641.3155 Prompt payment of claims.—

(10) A health maintenance organization may not retroactively deny a claim because of subscriber ineligibility:

(a) More than 1 year after the date of payment of the claim; or

(b) At any time, if the health maintenance organization verified the subscriber's eligibility at the time of treatment or provided an authorization number.

Section 7. Subsection (4) is added to section 641.3156, Florida Statutes, to read:

641.3156 Treatment authorization; payment of claims.—

(4) A health maintenance organization may not impose an additional prior authorization requirement with respect to a surgical or otherwise invasive procedure, or any item furnished as part of the surgical or invasive procedure, if the procedure or item is furnished during the perioperative period of another procedure for which prior authorization was granted by the health maintenance organization.

Section 8. This act shall take effect January 1, 2022.