A bill to be entitled

An act relating to insurance coverages for drugs and medical procedures and treatments; 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 have failed with a different drug; providing applicability; prohibiting insurers and health maintenance organizations from excluding coverage for certain drugs on certain grounds; prohibiting insurers and health maintenance organizations from requiring home infusion for certain cancer treatment drugs or that certain cancer treatment drugs be sent to certain entities for home infusion unless a certain condition is met; 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 approved by the Financial Services Commission; 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; 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 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 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) PROHIBITION ON MANDATORY HOME INFUSION.—An insurer or a health maintenance organization may not require that a cancer medication be administered using home infusion, and may not require that such medication be sent directly to a third party or to the patient for home infusion, unless the patient's

treating oncologist determines that home infusion of the cancer medication will not jeopardize the health of the patient.

(6) 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:

(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" means an injury or a 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) Notwithstanding any other ~~provision of~~ law, effective January 1, 2023 ~~January 1, 2017~~, or 6 ~~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 only 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 all of the following:

(a) ~~(1)~~ Sufficient patient information to identify the member, including 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 required 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 that information necessary for the determination of the 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.

Prior authorization.—

(5) A health insurer, or a pharmacy benefits manager on behalf of the health insurer, shall, upon request, provide the following information in electronic or paper 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 that 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) Insureds and health care providers 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, shall 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. This act shall take effect January 1, 2023.