A bill to be entitled

An act relating to health insurance coverage; amending s. 627.4239, F.S.; defining the terms "associated condition" and "health care provider"; prohibiting health maintenance organizations from excluding coverage for certain drugs on a specified ground; prohibiting insurers and health maintenance organizations of certain individual and group health insurance policies and health maintenance contracts from requiring, before certain drugs are covered, that an insured or subscriber undergo a step-therapy protocol or step-therapy override determination; providing applicability; prohibiting such insurers and health maintenance organizations from excluding coverage for certain drugs on a specified ground; requiring coverage for specified services; amending ss. 627.42393 and 641.31, F.S.; revising and providing definitions; requiring health coverage plans to provide on their websites an easily accessible process for requests for a step-therapy protocol override determination under certain circumstances; providing requirements and timeframes for the determination; requiring health coverage plans to grant requests to override step-therapy protocols under certain circumstances; requiring health coverage plans to

authorize coverage for a prescription drug prescribed by an insured's or subscriber's health care provider under certain circumstances; providing construction; amending s. 627.6131, F.S.; prohibiting health insurers from retroactively denying a claim because of insured ineligibility at any time under certain circumstances; prohibiting health insurers from imposing additional prior authorization requirements for certain procedures and items under certain circumstances; amending s. 641.3155, F.S.; prohibiting health maintenance organizations from retroactively denying at any time a claim because of subscriber ineligibility under certain circumstances; amending s. 641.3156, F.S.; prohibiting health maintenance organizations from imposing additional prior authorization requirements for certain procedures and items under certain circumstances; 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.

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) ~~(a)~~ "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) 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 a particular stage 4 metastatic cancer and its associated conditions, an insurer or a health maintenance organization may not require that, before a drug prescribed for the treatment is covered, the insured or subscriber undergo a step-therapy protocol or step-therapy override determination under s. 627.42393 or s. 641.31(46).

(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 the 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 under this section 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.

(b) Require coverage for any drug 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.

(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 627.42393, Florida Statutes, is amended to read:

627.42393 Step-therapy protocol.—

(1)~~(2)~~ 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)~~ A health insurer as defined in s. 627.42392 ~~or health maintenance organization~~.

2.~~(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.

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

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

(b) "Step-therapy override determination" means a determination by a health coverage plan that in a particular situation a step-therapy protocol should apply or it should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

(c) "Step-therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs determined as medically appropriate for an insured for a specified medical condition are covered by a health coverage plan.

(2)~~(1)~~ A health coverage plan under ~~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 current request.

(3)(a) If coverage of a prescription drug for the treatment of a medical condition is restricted for use by a health coverage plan through the use of a step-therapy protocol, the health coverage plan must provide a clear and convenient process for an insured and health care provider to request a step-therapy override determination. This process must be made easily accessible on the health coverage plan's website. The health coverage plan must provide a prescription drug for

treatment of the insured's medical condition at least until the step-therapy override determination is made.

(b) The health coverage plan must base the step-therapy override determination on a review of the insured's or health care provider's request for an override and the rationale and documentation supporting the request.

(c)1. When an insured or health care provider submits a request for a step-therapy override determination or submits an appeal of a step-therapy override determination decision, the health coverage plan must grant or deny the request or appeal within 24 hours after the submission in an urgent care situation and within 2 business days in a nonurgent care situation.

2. If the health coverage plan fails to respond in accordance with the timeframe established in subparagraph 1., the request or appeal shall be deemed approved.

(d) A health coverage plan must grant a request to override a step-therapy protocol in favor of the health care provider's selected prescription drug for any of the following reasons:

1. The prescription drug required under the step-therapy protocol is contraindicated, or it is not in the insured's best interest because the drug will likely:

a. Cause a significant barrier to the insured's adherence to, or compliance with, the insured's plan of care.

b. Be ineffective, based on the insured's medical history

and the clinical evidence of the known characteristics of the prescription drug regimen.

c. Cause an adverse reaction or physical or mental harm to the insured, including a worsened comorbid condition or a decrease in the insured's ability to achieve or maintain reasonable functional ability in performing daily activities.

2. The insured has tried, under his or her current health coverage plan, the required prescription drug or another prescription drug that is in the same pharmacologic class or that has the same mechanism of action, and such prescription drug lacked efficacy or effectiveness or adversely affected the insured.

3. The insured is stable on the health care provider's selected prescription drug for the medical condition under consideration.

(e) Upon granting a request to override a step-therapy protocol in favor of the health care provider's selected prescription drug, the health coverage plan must authorize immediate coverage of the selected prescription drug if the health coverage plan covers such prescription drug.

(4) This section does not prevent a health coverage plan from requiring an insured to try a generic equivalent before providing coverage for the equivalent brand-name prescription drug.

(5) ~~(3)~~ This section does not require a health coverage

plan ~~insurer~~ to add a drug to its prescription drug formulary or to cover a prescription drug that the health coverage plan ~~insurer~~ does not otherwise cover.

Section 3. 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) At any time, if the health insurer has confirmed insured eligibility at the time of treatment or has granted prior authorization for a treatment.

(b) Except as provided in paragraph (a), more than 1 year after the date of payment of the claim.

(20) A health insurer may not impose any additional prior authorization requirement with respect to a surgical or an otherwise invasive procedure and with respect to an item furnished as part of such surgical or invasive procedure, if such procedure or item is furnished:

(a) During the perioperative period of another procedure for which prior authorization from the health insurer was received.

(b) After the prior authorization described in paragraph (a) was received.

Section 4. Subsection (46) of section 641.31, Florida

Statutes, is amended to read:

641.31 Health maintenance contracts.—

(46) (a) ~~(b)~~ As used in this subsection, the term:

1. "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:

a. ~~1.~~ A health insurer as defined in s. 627.42392 ~~or health maintenance organization~~;

b. ~~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;

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

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

2. "Step-therapy override determination" means a determination by a health coverage plan that in a particular situation a step-therapy protocol should apply or it should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

3. "Step-therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs determined as medically appropriate for a subscriber for a specified medical condition are covered by a health coverage plan.

(b) ~~(a)~~ A health coverage plan under a ~~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 current request.

(c)1. If coverage of a prescription drug for the treatment of a medical condition is restricted for use by a health coverage plan through the use of a step-therapy protocol, the health coverage plan must provide a clear and convenient process for a subscriber and health care provider to request a step-therapy override determination. This process must be made easily accessible on the health coverage plan's website. The health coverage plan must provide a prescription drug for treatment of the subscriber's medical condition at least until the step-therapy override determination is made.

2. The health coverage plan must base the step-therapy override determination on a review of the subscriber's or health

care provider's request for an override and the subscriber's or health care provider's rationale and documentation supporting the request.

3.a. When a subscriber or health care provider submits a request for a step-therapy override determination or submits an appeal of a step-therapy override determination decision, the health coverage plan must grant or deny the request or appeal within 24 hours after the submission in an urgent care situation and within 2 business days in a nonurgent care situation.

b. If the health coverage plan fails to respond in accordance with the timeframe established in sub-subparagraph a., the request or appeal shall be deemed approved.

4. A health coverage plan must grant a request to override a step-therapy protocol in favor of the health care provider's selected prescription drug for any of the following reasons:

a. The prescription drug required under the step-therapy protocol is contraindicated, or it is not in the subscriber's best interest because the drug will likely:

(I) Cause a significant barrier to the subscriber's adherence to, or compliance with, the subscriber's plan of care.

(II) Be ineffective, based on the subscriber's medical history and the clinical evidence of the known characteristics of the prescription drug regimen.

(III) Cause an adverse reaction or physical or mental harm to the subscriber, including a worsened comorbid condition or a

decrease in the subscriber's ability to achieve or maintain reasonable functional ability in performing daily activities.

b. The subscriber has tried, under his or her current health coverage plan, the required prescription drug or another prescription drug that is in the same pharmacologic class or that has the same mechanism of action, and such prescription drug lacked efficacy or effectiveness or adversely affected the subscriber.

c. The subscriber is stable on the health care provider's selected prescription drug for the medical condition under consideration.

5. Upon granting a request to override a step-therapy protocol in favor of the health care provider's selected prescription drug, the health coverage plan must authorize immediate coverage of the selected prescription drug if the health coverage plan covers such prescription drug.

(d) This subsection does not prevent a health coverage plan from requiring a subscriber to try a generic equivalent before providing coverage for the brand-name prescription drug.

(e) ~~(c)~~ 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 5. 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) At any time, if the health maintenance organization has confirmed subscriber eligibility at the time of treatment or has granted prior authorization for the treatment.

(b) Except as provided in paragraph (a), more than 1 year after the date of payment of the claim.

Section 6. 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 any additional prior authorization requirement with respect to a surgical or an otherwise invasive procedure and with respect to an item furnished as part of such surgical or invasive procedure, if such procedure or item is furnished:

(a) During the perioperative period of another procedure for which prior authorization from the health maintenance organization was received.

(b) After the prior authorization described in paragraph (a) was received.

Section 7. This act shall take effect January 1, 2021.