A bill to be entitled

An act relating to health insurance coverage for biomarker testing; amending s. 409.905, F.S.; requiring the Agency for Health Care Administration to pay for biomarker testing under the Medicaid program under specified conditions; providing requirements for covered biomarker testing; requiring notification on utilization review request determinations within specified timeframes; requiring access to request process for exceptions to coverage and to certain adverse determinations; requiring such process to be posted on the agency's website; providing definitions; amending s. 409.973, F.S.; requiring managed care plans to cover biomarker testing under the Medicaid program; creating ss. 627.64094, 627.65742, 641.31078, and 641.5143, F.S.; requiring certain individual health insurance policies, group health insurance policies, health maintenance contracts, and prepaid health clinic contracts, respectively, and certain health services, health care, and health benefit plans to provide coverage for biomarker testing; providing requirements for covered biomarker testing; requiring notification on utilization review request determinations within specified timeframes; requiring access to request process for exceptions to coverage

and to certain adverse determinations; requiring such process to be posted on the entities' websites; providing an effective date.

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

Section 1. Subsection (2) of section 409.905, Florida Statutes, is amended to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(2) EARLY AND PERIODIC SCREENING, DIAGNOSIS, AND TREATMENT SERVICES; BIOMARKER TESTING.—

(a) The agency shall pay for early and periodic screening and diagnosis of a recipient under age 21 to ascertain physical and mental problems and conditions and all services determined by the agency to be medically necessary for the treatment, correction, or amelioration of these problems and conditions, including personal care, private duty nursing, durable medical equipment, physical therapy, occupational therapy, speech therapy, respiratory therapy, and immunizations.

(b) Subject to the approval of the Centers for Medicare and Medicaid Services, the agency shall pay for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a recipient's disease or condition.

1. The biomarker testing covered under this paragraph must be supported by medical and scientific evidence. Such evidence includes, but is not limited to:

a. Labeled indications for a United States Food and Drug Administration-approved or Food and Drug Administration-cleared test;

b. Indicated tests for a Food and Drug Administration-approved drug;

c. Warnings and precautions on Food and Drug Administration-approved drug labels;

d. The Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor

local coverage determinations; or

e. Nationally recognized clinical practice guidelines and consensus statements.

2. The biomarker testing covered under this paragraph must be provided in a manner that limits disruptions in care, including tests to remove multiple biopsies or biospecimen samples.

3. If utilization review, including, but not limited to, prior authorization, is required, the utilization review committee or any third party acting on behalf of the agency must approve or deny a utilization review request, including, but not limited to, a prior authorization request, and must notify the recipient, the recipient's health care provider, and any entity requesting authorization of the biomarker testing within 72 hours for a nonurgent request and within 24 hours for an urgent request after receipt of the request.

4. The recipient and the prescribing health care provider must have access to a clear, readily accessible, and convenient process to request an exception to the coverage or an adverse utilization review determination of the agency. The process shall be made readily accessible on the agency's website.

5. As used in this paragraph, the terms "biomarker," "biomarker testing," "consensus statements," and "nationally recognized practice guidelines" have the same meanings as in s. 627.64094.

Section 2. Paragraph (dd) is added to subsection (1) of section 409.973, Florida Statutes, to read:

409.973 Benefits.—

(1) MINIMUM BENEFITS.—Managed care plans shall cover, at a minimum, the following services:

(dd) Biomarker testing, as defined in s. 627.64094.

Section 3. Section 627.64094, Florida Statutes, is created to read:

627.64094 Coverage for biomarker testing.—

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

(a) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. The term includes, but is not limited to, gene mutations, characteristics of genes, and protein expression.

(b) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(c) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts using a

transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(d) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(2) A health insurance policy, a nonprofit health services plan or nonprofit health care plan, as defined in s. 628.703, and a health benefit plan, as defined in s. 627.6699(3), issued, amended, delivered, or renewed in this state, or providing prepaid health care in this state, on or after July 1, 2023, must include coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition.

(a) The biomarker testing covered under this subsection must be supported by medical and scientific evidence. Such evidence includes, but is not limited to:

1. Labeled indications for a United States Food and Drug Administration-approved or Food and Drug Administration-cleared test;

2. Indicated tests for a Food and Drug Administration-approved drug;

3. Warnings and precautions on Food and Drug Administration-approved drug labels;

4. The Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations; or

5. Nationally recognized clinical practice guidelines and consensus statements.

(b) The biomarker testing covered under this subsection must be provided in a manner that limits disruptions in care, including tests to remove multiple biopsies or biospecimen samples.

(c) If utilization review, including, but not limited to, prior authorization, is required, the utilization review committee or any third party acting on behalf of the health insurer, the nonprofit health services plan or nonprofit health care plan, and the health benefit plan subject to this subsection must approve or deny a utilization review request, including, but not limited to, a prior authorization request, and must notify the insured, the insured's health care provider, and any entity requesting authorization of the biomarker testing

within 72 hours for a nonurgent request and within 24 hours for an urgent request after receipt of the request.

(e) The insured and the prescribing health care provider must have access to a clear, readily accessible, and convenient process to request an exception to the policy coverage or an adverse utilization review determination of the health insurer, the nonprofit health services plan or nonprofit health care plan, and the health benefit plan. The process shall be made readily accessible on the website of the health insurer, the nonprofit health services plan or nonprofit health care plan, and the health benefit plan.

Section 4. Section 627.65742, Florida Statutes, is created to read:

627.65742 Coverage for biomarker testing.—

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

(a) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. The term includes, but is not limited to, gene mutations, characteristics of genes, and protein expression.

(b) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a

biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(c) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(d) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(2) A health insurance policy, a nonprofit health services plan or nonprofit health care plan, as defined in s. 628.703, and a health benefit plan, as defined in s. 627.6699(3), issued, amended, delivered, or renewed in this state, or providing prepaid health care in this state, on or after July 1, 2023, must include coverage for biomarker testing for the purposes of

diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition.

(a) The biomarker testing covered under this subsection must be supported by medical and scientific evidence. Such evidence includes, but is not limited to:

1. Labeled indications for a United States Food and Drug Administration-approved or Food and Drug Administration-cleared test;

2. Indicated tests for a Food and Drug Administration-approved drug;

3. Warnings and precautions on Food and Drug Administration-approved drug labels;

4. The Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations; or

5. Nationally recognized clinical practice guidelines and consensus statements.

(b) The biomarker testing covered under this subsection must be provided in a manner that limits disruptions in care, including tests to remove multiple biopsies or biospecimen samples.

(c) If utilization review, including, but not limited to, prior authorization, is required, the utilization review committee or any third party acting on behalf of the health insurer, the nonprofit health services plan or nonprofit health

care plan, and the health benefit plan subject to this subsection must approve or deny a utilization review request, including, but not limited to, a prior authorization request, and must notify the insured, the insured's health care provider, and any entity requesting authorization of the biomarker testing within 72 hours for a nonurgent request and within 24 hours for an urgent request after receipt of the request.

(e) The insured and the prescribing health care provider must have access to a clear, readily accessible, and convenient process to request an exception to the policy coverage or an adverse utilization review determination of the health insurer, the nonprofit health services plan or nonprofit health care plan, and the health benefit plan. The process shall be made readily accessible on the website of the health insurer, the nonprofit health services plan or nonprofit health care plan, and the health benefit plan.

Section 5. Section 641.31078, Florida Statutes, is created to read:

641.31078 Coverage for biomarker testing.—

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

(a) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already

being administered. The term includes, but is not limited to, gene mutations, characteristics of genes, and protein expression.

(b) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(c) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(d) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(2) A health maintenance contract, a nonprofit health

services plan or nonprofit health care plan, as defined in s. 628.703, and a health benefit plan, as defined in s. 627.6699(3), issued, amended, delivered, or renewed in this state, or providing prepaid health care in this state, on or after July 1, 2023, must include coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a subscriber's disease or condition.

(a) The biomarker testing covered under this subsection must be supported by medical and scientific evidence. Such evidence includes, but is not limited to:

1. Labeled indications for a United States Food and Drug Administration-approved or Food and Drug Administration-cleared test;

2. Indicated tests for a Food and Drug Administration-approved drug;

3. Warnings and precautions on Food and Drug Administration-approved drug labels;

4. The Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations; or

5. Nationally recognized clinical practice guidelines and consensus statements.

(b) The biomarker testing covered under this subsection must be provided in a manner that limits disruptions in care,

including tests to remove multiple biopsies or biospecimen samples.

(c) If utilization review, including, but not limited to, prior authorization, is required, the utilization review committee or any third party acting on behalf of the health maintenance organization, the nonprofit health services plan or nonprofit health care plan, and the health benefit plan subject to this subsection must approve or deny a utilization review request, including, but not limited to, a prior authorization request, and must notify the subscriber, the subscriber's health care provider, and any entity requesting authorization of the biomarker testing within 72 hours for a nonurgent request and within 24 hours for an urgent request after receipt of the request.

(e) The subscriber and the prescribing health care provider must have access to a clear, readily accessible, and convenient process to request an exception to the contract coverage or an adverse utilization review determination of the health maintenance organization, the nonprofit health services plan or nonprofit health care plan, and the health benefit plan. The process shall be made readily accessible on the website of the health maintenance organization, the nonprofit health services plan or nonprofit health care plan, and the health benefit plan.

Section 6. Section 641.5143, Florida Statutes, is created

to read:

641.5143 Coverage for biomarker testing.—

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

(a) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. The term includes, but is not limited to, gene mutations, characteristics of genes, and protein expression.

(b) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(c) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.

(d) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by

independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(2) A prepaid health clinic contract issued, amended, delivered, or renewed in the state on or after July 1, 2023, must include coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a subscriber's disease or condition.

(a) The biomarker testing covered under this subsection must be supported by medical and scientific evidence. Such evidence includes, but is not limited to:

1. Labeled indications for a United States Food and Drug Administration-approved or Food and Drug Administration-cleared test;

2. Indicated tests for a Food and Drug Administration-approved drug;

3. Warnings and precautions on Food and Drug Administration-approved drug labels;

4. The Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations; or

5. Nationally recognized clinical practice guidelines and consensus statements.

(b) The biomarker testing covered under this subsection must be provided in a manner that limits disruptions in care, including tests to remove multiple biopsies or biospecimen samples.

(c) If utilization review, including, but not limited to, prior authorization, is required, the utilization review committee or any third party acting on behalf of the prepaid health clinic subject to this subsection must approve or deny a utilization review request, including, but not limited to, a prior authorization request, and must notify the subscriber, the subscriber's health care provider, and any entity requesting authorization of the biomarker testing within 72 hours for a nonurgent request and within 24 hours for an urgent request after receipt of the request.

(e) The subscriber and the prescribing health care provider must have access to a clear, readily accessible, and convenient process to request an exception to the contract coverage or an adverse utilization review determination of the prepaid health clinic. The process shall be made readily accessible on the prepaid health clinic's website.

Section 7. This act shall take effect July 1, 2023.