A bill to be entitled

An act relating to coverage for biomarker testing; amending s. 409.906, F.S.; authorizing the Agency for Health Care Administration to pay for biomarker testing under the Medicaid program for specified purposes, subject to specific appropriations; specifying circumstances under which such payments may be made; providing definitions; requiring a clear, readily accessible, and convenient process for authorization requests for biomarker testing; providing construction; authorizing the agency to seek federal approval for biomarker testing payments; creating s. 409.9745, F.S.; requiring managed care plans under contract with the agency to provide services in the Medicaid program to provide coverage for biomarker testing for Medicaid recipients in a certain manner; requiring a clear, readily accessible, and convenient process for authorization requests for biomarker testing; providing construction; creating ss. 627.64183, 627.66133, and 641.31093, F.S.; providing definitions; requiring certain individual health insurance policies; group, blanket, and franchise health insurance policies; and health maintenance contracts, respectively, to provide coverage for biomarker testing for certain purposes;

specifying circumstances under which such coverage may be provided; requiring a clear, readily accessible, and convenient process for authorization requests for biomarker testing; providing construction; providing an effective date.

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

Section 1. Subsection (29) is added to section 409.906, Florida Statutes, to read:

409.906 Optional Medicaid services.—Subject to specific appropriations, the agency may make payments for services which are optional to the state under Title XIX of the Social Security Act and are furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any optional service that is provided shall be provided only when medically necessary and in accordance with state and federal law. Optional services rendered by providers in mobile units to Medicaid recipients may be restricted or prohibited 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, or number of services, or making 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. If necessary to safeguard the state's systems of providing services to elderly and disabled persons and subject to the notice and review provisions of s. 216.177, the Governor may direct the Agency for Health Care Administration to amend the Medicaid state plan to delete the optional Medicaid service known as "Intermediate Care Facilities for the Developmentally Disabled." Optional services may include:

(29) BIOMARKER TESTING SERVICES.—

(a) The agency may pay for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a recipient's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the recipient. Such medical and scientific evidence includes, but is not limited to:

1. A labeled indication for a test approved or cleared by the Unites States Food and Drug Administration;

2. An indicated test for a drug approved by the United States Food and Drug Administration;

3. A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

4. A nationally recognized clinical practice guideline. As used in this subparagraph, the term "nationally recognized clinical practice guideline" means an evidence-based clinical

practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

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

1. "Biomarker" means a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. The term includes, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

2. "Biomarker testing" means an 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 performed at a participating in-network laboratory facility that is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA

Certificate of Waiver by the United States Food and Drug Administration for the tests.

3. "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(c) A recipient and participating provider shall have access to a clear and convenient process to request authorization for biomarker testing as provided under this subsection. Such process shall be made readily accessible to all recipients and participating providers online.

(d) This subsection does not require coverage of biomarker testing for screening purposes.

(e) The agency may seek federal approval necessary to implement this subsection.

Section 2. Section 409.9745, Florida Statutes, is created to read:

409.9745 Managed care plan biomarker testing.—

(1) A managed care plan must provide coverage for biomarker testing for recipients, as authorized under s. 409.906, at the same scope, duration, and frequency as the Medicaid program provides for other medically necessary treatments.

(2) A recipient and health care provider shall have access to a clear and convenient process to request authorization for

biomarker testing as provided under this section. Such process shall be made readily accessible on the website of the managed care plan.

(3) This section does not require coverage of biomarker testing for screening purposes.

Section 3. Section 627.64183, Florida Statutes, is created to read:

627.64183 Coverage for biomarker testing.—

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

(a) "Biomarker" means a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. The term includes, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

(b) "Biomarker testing" means an 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 performed at a participating in-network laboratory facility that is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA

Certificate of Waiver by the United States Food and Drug Administration for the tests.

(c) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(2) A health insurance policy or a nonprofit health service plan that covers a resident of this state and that is issued, amended, delivered, or renewed in this state on or after January 1, 2025, must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the insured. Such medical and scientific evidence includes, but is not limited to:

(a) A labeled indication for a test approved or cleared by the Unites States Food and Drug Administration;

(b) An indicated test for a drug approved by the United States Food and Drug Administration;

(c) A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

(d) A nationally recognized clinical practice guideline. As used in this paragraph, the term "nationally recognized

clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

(3) The coverage under subsection (2) shall be provided in a manner that limits disruptions in care, including, but not limited to, the need for multiple biopsies or biospecimen samples.

(4) The insured and the insured's ordering or prescribing health care provider shall have access to a clear and convenient process to request authorization for biomarker testing as provided under this section. Such process shall be made readily accessible on the website of the health insurer and nonprofit health service plan.

(5) This section does not require coverage of biomarker testing for screening purposes.

Section 4. Section 627.66133, Florida Statutes, is created to read:

627.66133 Coverage for biomarker testing.—

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

(a) "Biomarker" means a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. The term includes, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

(b) "Biomarker testing" means an 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 performed at a participating in-network laboratory facility that is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA Certificate of Waiver by the United States Food and Drug Administration for the tests.

(c) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(2) A group, blanket, or franchise health insurance policy or a nonprofit health service plan that covers a resident of this state and that is issued, amended, delivered, or renewed in

this state on or after January 1, 2025, must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the insured. Such medical and scientific evidence includes, but is not limited to:

(a) A labeled indication for a test approved or cleared by the Unites States Food and Drug Administration;

(b) An indicated test for a drug approved by the United States Food and Drug Administration;

(c) A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

(d) A nationally recognized clinical practice guideline. As used in this paragraph, the term "nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

(3) The coverage under subsection (2) shall be provided in a manner that limits disruptions in care, including, but not limited to, the need for multiple biopsies or biospecimen samples.

(4) The insured and the insured's ordering or prescribing health care provider shall have access to a clear and convenient process to request authorization for biomarker testing as provided under this section. Such process shall be made readily accessible on the website of the health insurer and nonprofit health service plan.

(5) This section does not require coverage of biomarker testing for screening purposes.

Section 5. Section 641.31093, Florida Statutes, is created to read:

641.31093 Coverage for biomarker testing.—

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

(a) "Biomarker" means a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. The term includes, but is not limited to, molecular, histologic, radiographic, or physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

(b) "Biomarker testing" means an 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 performed at a participating in-network laboratory facility that is certified pursuant to the federal Clinical Laboratory Improvement Amendment (CLIA) or that has obtained a CLIA Certificate of Waiver by the United States Food and Drug Administration for the tests.

(c) "Clinical utility" means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

(2) A health maintenance contract or a nonprofit health service plan that covers a resident of this state and that is issued, amended, delivered, or renewed in this state on or after January 1, 2025, must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a subscriber's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the subscriber. Such medical and scientific evidence includes, but is not limited to:

(a) A labeled indication for a test approved or cleared by the Unites States Food and Drug Administration;

(b) An indicated test for a drug approved by the United States Food and Drug Administration;

(c) A national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by the Medicare Administrative Contractor; or

(d) A nationally recognized clinical practice guideline. As used in this paragraph, the term "nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Guidelines developed by such organizations or societies establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

(3) The coverage under subsection (2) shall be provided in a manner that limits disruptions in care, including, but not limited to, the need for multiple biopsies or biospecimen samples.

(4) The subscriber and the subscriber's ordering or prescribing health care provider shall have access to a clear and convenient process to request authorization for biomarker testing as provided under this section. Such process shall be made readily accessible on the website of the health maintenance

organization and nonprofit health service plan.

(5) This section does not require coverage of biomarker testing for screening purposes.

Section 6. This act shall take effect July 1, 2024.