By Senator Calatayud

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A bill to be entitled

An act relating to coverage of biomarker testing; amending s. 409.905, F.S.; defining terms; requiring the Agency for Health Care Administration to provide specified coverage of biomarker testing under the Medicaid program; requiring managed care plans under contract with the agency to provide coverage of biomarker testing in a specified manner; requiring the agency to provide a clear, readily accessible, and convenient process for Medicaid recipients and providers to request an exception to the coverage; requiring that such process be made available in an online format on the agency's website; providing construction; creating ss. 627.64055 and 641.31708, F.S.; defining terms; requiring that certain health insurance policies and health maintenance contracts, respectively, provide specified coverage of biomarker testing; requiring that such coverage be provided in a manner that limits disruption in care; requiring insurers and health maintenance organizations, respectively, to provide a clear, readily accessible, and convenient process for covered individuals and ordering or prescribing practitioners to request an exception to the coverage; requiring that such process be made available on the insurers' and health maintenance organizations' respective websites; providing construction; providing an effective date.

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

Section 1. Subsection (13) is added to section 409.905, Florida Statutes, 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.

(13) BIOMARKER TESTING SERVICES.—

(a) 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 molecular, histologic, radiographic, and physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

2. "Biomarker testing" means 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 performed at a participating in-network laboratory facility that the Centers for Medicare and Medicaid Services has either certified or granted a waiver under the federal Clinical Laboratory Improvement Amendments of 1988.

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

4. "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. Clinical practice guidelines 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) The agency shall pay for biomarker testing for diagnosis, treatment, management, and ongoing monitoring of a recipient's disease or condition to guide treatment decisions when such testing provides clinical utility to the recipient and is demonstrated by medical and scientific evidence, including, but not limited to, any of the following:

1. Labeled indications for a test approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.

2. Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.

3. Nationally recognized clinical practice guidelines.

(c) Managed care plans under contract with the agency to deliver services to recipients shall provide biomarker testing at the same scope, duration, and frequency as the Medicaid program otherwise provides to enrollees.

(d) The agency shall provide a clear, readily accessible, and convenient process for Medicaid recipients and providers to request an exception to a coverage policy under the Medicaid program or of managed care plans under contract with the agency to provide services to enrollees. Such process must be made available in an online format on the agency's website.

(e) This subsection may not be construed to require coverage of biomarker testing for screening purposes.

Section 2. Section 627.64055, Florida Statutes, is created to read:

627.64055 Coverage of 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 molecular, histologic, radiographic, and physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

(b) "Biomarker testing" means 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 performed at a participating in-network laboratory facility that the Centers for Medicare and Medicaid Services has either certified or granted a waiver under the federal Clinical Laboratory Improvement Amendments of 1988.

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

(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. Clinical practice guidelines 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.

(2) A health insurance policy 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, and ongoing monitoring of an insured's disease or condition to guide treatment decisions when the testing provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to, any of the following:

(a) Labeled indications for a test approved or cleared by

the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.

(b) Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.

(c) Nationally recognized clinical practice guidelines.

(3) Coverage of biomarker testing must be provided in a manner that limits disruptions in care, including the taking of multiple biopsies or biospecimen samples.

(4) The insurer shall provide a clear, readily accessible, and convenient process for insureds and ordering or prescribing practitioners to request an exception to coverage of biomarker testing in an insurance policy. Such process must be made available in an online format on the insurer's website.

(5) This section may not be construed to require coverage of biomarker testing for screening purposes.

Section 3. Section 641.31708, Florida Statutes, is created to read:

641.31708 Coverage of 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 molecular, histologic, radiographic, and physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.

(b) "Biomarker testing" means 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 performed at a participating in-network laboratory facility that the Centers for Medicare and Medicaid Services has either certified or granted a waiver under the federal Clinical Laboratory Improvement Amendments of 1988.

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

(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. Clinical practice guidelines 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.

(2) A health maintenance contract 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, and ongoing monitoring of a subscriber's disease or condition to guide treatment decisions when the testing provides clinical utility to the patient as demonstrated by medical and scientific evidence, including, but not limited to, any of the following:

(a) Labeled indications for a test approved or cleared by

the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.

(b) Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.

(c) Nationally recognized clinical practice guidelines.

(3) Coverage of biomarker testing must be provided in a manner that limits disruptions in care, including the taking of multiple biopsies or biospecimen samples.

(4) The health maintenance organization shall provide a clear, readily accessible, and convenient process for subscribers and ordering or prescribing practitioners to request an exception to coverage of biomarker testing in a health maintenance contract. Such process must be made available in an online format on the health maintenance organization's website.

(5) This section may not be construed to require coverage of biomarker testing for screening purposes.

Section 4. This act shall take effect July 1, 2024.