An act relating to coverage for biomarker testing; amending s. 110.12303, F.S.; requiring the Department of Management Services to provide coverage of biomarker testing for specified purposes for state employees' state group health insurance plan policies issued on or after a specified date; specifying circumstances under which such coverage may be provided; providing definitions; requiring a clear, convenient, and readily accessible process for authorization requests for biomarker testing; providing construction; 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, convenient, and readily accessible 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 in the Medicaid program to provide coverage for biomarker testing for Medicaid recipients in a certain manner;

requiring a clear, convenient, and readily accessible process for authorization requests for biomarker testing; providing construction; requiring the agency to include a certain rate impact in specified Medicaid program rates; providing effective dates.

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

Section 1. Subsection (5) is added to section 110.12303, Florida Statutes, to read:

110.12303 State group insurance program; additional benefits; price transparency program; reporting.—

(5)(a) For state group health insurance plan policies issued on or after January 1, 2025, the department shall provide coverage of biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions if medical and scientific evidence indicates that the biomarker testing provides clinical utility to the enrollee. Such medical and scientific evidence includes, but is not limited to:

1. A labeled indication for a test approved or cleared by the United 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) Each state group health insurance plan shall provide a clear and convenient process for providers to request authorization for biomarker testing. Such process shall be made readily accessible to all enrollees and participating providers online.

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

Section 2. 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 3. Effective October 1, 2024, 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.

(4) The agency shall include the rate impact of this section in the applicable Medicaid managed medical assistance program and long-term care managed care program rates.

Section 4. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2024.