CHAMBER ACTION

Senate House

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Representative Gonzalez Pittman offered the following:

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Amendment (with title amendment)

4 Remove lines 93-189 and insert:

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

718117

Approved For Filing: 2/27/2024 12:13:06 PM

Page 1 of 5

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:

89	409.9745 Managed care plan biomarker testing
90	(1) A managed care plan must provide coverage for
91	biomarker testing for recipients, as authorized under s.
92	409.906, at the same scope, duration, and frequency as the
93	Medicaid program provides for other medically necessary
94	<u>treatments.</u>
95	(2) A recipient and health care provider shall have access
96	to a clear and convenient process to request authorization for
97	biomarker testing as provided under this section. Such process
98	shall be made readily accessible on the website of the managed
99	care plan.
100	(3) This section does not require coverage of biomarker
101	testing for screening purposes.
102	(4) The agency shall include the rate impact of this
103	section in the applicable Medicaid managed medical assistance
104	program and long-term care managed care program rates.
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107	TITLE AMENDMENT
108	Remove line 28 and insert:
109	testing; providing construction; requiring the agency
110	to include a certain rate impact in specified Medicaid
111	program rates; providing effective

718117