A bill to be entitled

An act relating to biomarker testing; amending s. 409.906, F.S.; revising the definition of the term "biomarker testing"; requiring the Agency for Health Care Administration to establish a provider reimbursement schedule and billing codes for a specified medical services and procedures coding to cover biomarker testing; authorizing Medicaid program coverage of certain colorectal cancer tests; amending s. 409.9745, F.S.; requiring Medicaid managed care plans to cover certain colorectal cancer tests at a certain level; requiring the agency to contract for a cost-benefit analysis; providing requirements for the analysis; providing reporting requirements; providing for future repeal; providing an effective date.

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

Section 1. Paragraphs (b), (c), and (d) of subsection (29) of section 409.906, Florida Statutes, are amended 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.—

(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 that are:

a. Billed under either Current Procedural Terminology or Proprietary Laboratory Analyses codes; and

b. 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. By August 1, 2025, the agency shall establish a provider reimbursement

schedule and billing codes for the Proprietary Laboratory Analyses codes to cover biomarker testing as provided in this subsection.

(d) This subsection does not require coverage of biomarker testing for screening purposes. The agency may pay for medically necessary blood-based biomarker tests for colorectal cancer screening.

Section 2. Section 409.9745, Florida Statutes, is amended 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.

(a) ~~(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.

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

(c) ~~(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.

(2) A managed care plan must provide coverage for medically necessary blood-based biomarker tests for colorectal cancer screening at the same scope and frequency as the Medicaid program provides for other medically necessary tests or screenings for colorectal cancer.

Section 3. The Agency for Health Care Administration must contract for an independent, actuarially sound 5-year comparative cost-benefit analysis of the cost-effectiveness of providing coverage of blood-based biomarker tests for colorectal cancer in the Medicaid program. The analysis must address, at a minimum, the following factors:

(1) Data on the utilization of blood-based biomarker tests for colorectal cancer screening and other tests or screenings for colorectal cancer, including fecal immunochemical tests, fecal occult blood tests, stool DNA tests, and colonoscopies, and the total costs of such tests or screenings, broken out by type.

(2) Numeric and demographic data on recipients who received inpatient or outpatient treatment for colorectal cancer, total costs of such treatment, and total costs of other medically necessary care provided which was related to the colorectal cancer diagnosis.

(3) Data on cost avoidance, if any, attributable to the use of blood-based biomarker tests for colorectal cancer, including, but not limited to, cost avoidance due to

substitution for more costly tests and due to reductions in treatment cost attributable to earlier diagnosis.

(4) Data on deaths of Medicaid recipients attributable to colorectal cancer or a complication from colorectal cancer over the term of the study.

The agency must submit an interim report by November 30, 2028, and a final report by November 30, 2030, respectively, to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

Section 4. The provisions of this act amending s. 409.906(29)(d), Florida Statutes, and s. 409.9745, Florida Statutes, shall stand repealed on July 1, 2031, unless saved from repeal through reenactment by the Legislature.

Section 5. This act shall take effect upon becoming a law.