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2024 Legislature

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 2 An act relating to coverage for biomarker testing;
 3 amending s. 110.12303, F.S.; requiring the Department
 4 of Management Services to provide coverage of
 5 biomarker testing for specified purposes for state
 6 employees' state group health insurance plan policies
 7 issued on or after a specified date; specifying
 8 circumstances under which such coverage may be
 9 provided; providing definitions; requiring a clear,
 10 convenient, and readily accessible process for
 11 authorization requests for biomarker testing;
 12 providing construction; amending s. 409.906, F.S.;
 13 authorizing the Agency for Health Care Administration
 14 to pay for biomarker testing under the Medicaid
 15 program for specified purposes, subject to specific
 16 appropriations; specifying circumstances under which
 17 such payments may be made; providing definitions;
 18 requiring a clear, convenient, and readily accessible
 19 process for authorization requests for biomarker
 20 testing; providing construction; authorizing the
 21 agency to seek federal approval for biomarker testing
 22 payments; creating s. 409.9745, F.S.; requiring
 23 managed care plans under contract with the agency in
 24 the Medicaid program to provide coverage for biomarker
 25 testing for Medicaid recipients in a certain manner;

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

31
 32 Be It Enacted by the Legislature of the State of Florida:

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

36 110.12303 State group insurance program; additional
 37 benefits; price transparency program; reporting.—

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

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

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

50 3. A national coverage determination made by the Centers

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51 for Medicare and Medicaid Services or a local coverage
52 determination made by the Medicare Administrative Contractor; or
53 4. A nationally recognized clinical practice guideline. As
54 used in this subparagraph, the term "nationally recognized
55 clinical practice guideline" means an evidence-based clinical
56 practice guideline developed by independent organizations or
57 medical professional societies using a transparent methodology
58 and reporting structure and with a conflict-of-interest policy.
59 Guidelines developed by such organizations or societies
60 establish standards of care informed by a systematic review of
61 evidence and an assessment of the benefits and costs of
62 alternative care options and include recommendations intended to
63 optimize patient care.

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

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

73 2. "Biomarker testing" means an analysis of a patient's
74 tissue, blood, or other biospecimen for the presence of a
75 biomarker. The term includes, but is not limited to, single

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76 analyte tests, multiplex panel tests, protein expression, and
 77 whole exome, whole genome, and whole transcriptome sequencing
 78 performed at a participating in-network laboratory facility that
 79 is certified pursuant to the federal Clinical Laboratory
 80 Improvement Amendment (CLIA) or that has obtained a CLIA
 81 Certificate of Waiver by the United States Food and Drug
 82 Administration for the tests.

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

87 (c) Each state group health insurance plan shall provide a
 88 clear and convenient process for providers to request
 89 authorization for biomarker testing. Such process shall be made
 90 readily accessible to all enrollees and participating providers
 91 online.

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

94 Section 2. Subsection (29) is added to section 409.906,
 95 Florida Statutes, to read:

96 409.906 Optional Medicaid services.—Subject to specific
 97 appropriations, the agency may make payments for services which
 98 are optional to the state under Title XIX of the Social Security
 99 Act and are furnished by Medicaid providers to recipients who
 100 are determined to be eligible on the dates on which the services

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101 | were provided. Any optional service that is provided shall be
 102 | provided only when medically necessary and in accordance with
 103 | state and federal law. Optional services rendered by providers
 104 | in mobile units to Medicaid recipients may be restricted or
 105 | prohibited by the agency. Nothing in this section shall be
 106 | construed to prevent or limit the agency from adjusting fees,
 107 | reimbursement rates, lengths of stay, number of visits, or
 108 | number of services, or making any other adjustments necessary to
 109 | comply with the availability of moneys and any limitations or
 110 | directions provided for in the General Appropriations Act or
 111 | chapter 216. If necessary to safeguard the state's systems of
 112 | providing services to elderly and disabled persons and subject
 113 | to the notice and review provisions of s. 216.177, the Governor
 114 | may direct the Agency for Health Care Administration to amend
 115 | the Medicaid state plan to delete the optional Medicaid service
 116 | known as "Intermediate Care Facilities for the Developmentally
 117 | Disabled." Optional services may include:

118 | (29) BIOMARKER TESTING SERVICES.—

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

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126 1. A labeled indication for a test approved or cleared by
 127 the Unites States Food and Drug Administration;
 128 2. An indicated test for a drug approved by the United
 129 States Food and Drug Administration;
 130 3. A national coverage determination made by the Centers
 131 for Medicare and Medicaid Services or a local coverage
 132 determination made by the Medicare Administrative Contractor; or
 133 4. A nationally recognized clinical practice guideline. As
 134 used in this subparagraph, the term "nationally recognized
 135 clinical practice guideline" means an evidence-based clinical
 136 practice guideline developed by independent organizations or
 137 medical professional societies using a transparent methodology
 138 and reporting structure and with a conflict-of-interest policy.
 139 Guidelines developed by such organizations or societies
 140 establish standards of care informed by a systematic review of
 141 evidence and an assessment of the benefits and costs of
 142 alternative care options and include recommendations intended to
 143 optimize patient care.
 144 (b) As used in this subsection, the term:
 145 1. "Biomarker" means a defined characteristic that is
 146 measured as an indicator of normal biological processes,
 147 pathogenic processes, or responses to an exposure or
 148 intervention, including therapeutic interventions. The term
 149 includes, but is not limited to, molecular, histologic,
 150 radiographic, or physiologic characteristics but does not

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151 include an assessment of how a patient feels, functions, or
152 survives.

153 2. "Biomarker testing" means an analysis of a patient's
154 tissue, blood, or other biospecimen for the presence of a
155 biomarker. The term includes, but is not limited to, single
156 analyte tests, multiplex panel tests, protein expression, and
157 whole exome, whole genome, and whole transcriptome sequencing
158 performed at a participating in-network laboratory facility that
159 is certified pursuant to the federal Clinical Laboratory
160 Improvement Amendment (CLIA) or that has obtained a CLIA
161 Certificate of Waiver by the United States Food and Drug
162 Administration for the tests.

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

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

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

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

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176 Section 3. Effective October 1, 2024, section 409.9745,
 177 Florida Statutes, is created to read:

178 409.9745 Managed care plan biomarker testing.-

179 (1) A managed care plan must provide coverage for
 180 biomarker testing for recipients, as authorized under s.
 181 409.906, at the same scope, duration, and frequency as the
 182 Medicaid program provides for other medically necessary
 183 treatments.

184 (2) A recipient and health care provider shall have access
 185 to a clear and convenient process to request authorization for
 186 biomarker testing as provided under this section. Such process
 187 shall be made readily accessible on the website of the managed
 188 care plan.

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

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

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