

By the Appropriations Committee on Health and Human Services;
the Committee on Banking and Insurance; and Senator Calatayud

603-03307-24

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

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30 requiring managed care plans to provide Medicaid
31 recipients and health care providers with a clear and
32 convenient process for authorization requests for
33 biomarker testing; requiring that such process be
34 readily accessible on the managed care plan's website;
35 providing construction; requiring the agency to
36 include the rate impact of the act in certain rates
37 that become effective on a specified date; providing
38 an effective date.

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

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

44 110.12303 State group insurance program; additional
45 benefits; price transparency program; reporting.—

46 (5) (a) As used in this subsection, the term:

47 1. "Biomarker" means a defined characteristic that is
48 measured as an indicator of normal biological processes,
49 pathogenic processes, or responses to an exposure or
50 intervention, including therapeutic interventions. The term
51 includes, but is not limited to, molecular, histologic,
52 radiographic, or physiologic characteristics but does not
53 include an assessment of how a patient feels, functions, or
54 survives.

55 2. "Biomarker testing" means an analysis of a patient's
56 tissue, blood, or other biospecimen for the presence of a
57 biomarker. The term includes, but is not limited to, single
58 analyte tests, multiplex panel tests, protein expression, and

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59 whole exome, whole genome, and whole transcriptome sequencing
60 performed at a participating in-network laboratory facility that
61 is certified pursuant to the federal Clinical Laboratory
62 Improvement Amendment (CLIA) or that has obtained a CLIA
63 Certificate of Waiver by the United States Food and Drug
64 Administration for the tests.

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

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

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

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

81 3. A national coverage determination made by the Centers
82 for Medicare and Medicaid Services or a local coverage
83 determination made by the Medicare Administrative Contractor; or

84 4. A nationally recognized clinical practice guideline. As
85 used in this subparagraph, the term "nationally recognized
86 clinical practice guideline" means an evidence-based clinical
87 practice guideline developed by independent organizations or

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88 medical professional societies using a transparent methodology
89 and reporting structure and with a conflict-of-interest policy.
90 Guidelines developed by such organizations or societies
91 establish standards of care informed by a systematic review of
92 evidence and an assessment of the benefits and costs of
93 alternative care options and include recommendations intended to
94 optimize patient care.

95 (c) Each state group health insurance plan shall provide
96 enrollees and participating providers with a clear and
97 convenient process to request authorization for biomarker
98 testing. Such process must be made readily accessible online to
99 all enrollees and participating providers.

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

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

104 409.906 Optional Medicaid services.—Subject to specific
105 appropriations, the agency may make payments for services which
106 are optional to the state under Title XIX of the Social Security
107 Act and are furnished by Medicaid providers to recipients who
108 are determined to be eligible on the dates on which the services
109 were provided. Any optional service that is provided shall be
110 provided only when medically necessary and in accordance with
111 state and federal law. Optional services rendered by providers
112 in mobile units to Medicaid recipients may be restricted or
113 prohibited by the agency. Nothing in this section shall be
114 construed to prevent or limit the agency from adjusting fees,
115 reimbursement rates, lengths of stay, number of visits, or
116 number of services, or making any other adjustments necessary to

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117 comply with the availability of moneys and any limitations or
118 directions provided for in the General Appropriations Act or
119 chapter 216. If necessary to safeguard the state's systems of
120 providing services to elderly and disabled persons and subject
121 to the notice and review provisions of s. 216.177, the Governor
122 may direct the Agency for Health Care Administration to amend
123 the Medicaid state plan to delete the optional Medicaid service
124 known as "Intermediate Care Facilities for the Developmentally
125 Disabled." Optional services may include:

126 (29) BIOMARKER TESTING SERVICES.-

127 (a) As used in this subsection, the term:

128 1. "Biomarker" means a defined characteristic that is
129 measured as an indicator of normal biological processes,
130 pathogenic processes, or responses to an exposure or
131 intervention, including therapeutic interventions. The term
132 includes, but is not limited to, molecular, histologic,
133 radiographic, or physiologic characteristics but does not
134 include an assessment of how a patient feels, functions, or
135 survives.

136 2. "Biomarker testing" means an analysis of a patient's
137 tissue, blood, or other biospecimen for the presence of a
138 biomarker. The term includes, but is not limited to, single
139 analyte tests, multiplex panel tests, protein expression, and
140 whole exome, whole genome, and whole transcriptome sequencing
141 performed at a participating in-network laboratory facility that
142 is certified pursuant to the federal Clinical Laboratory
143 Improvement Amendment (CLIA) or that has obtained a CLIA
144 Certificate of Waiver by the United States Food and Drug
145 Administration for the tests.

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

150 (b) The agency may pay for biomarker testing for the
151 purposes of diagnosis, treatment, appropriate management, or
152 ongoing monitoring of a recipient's disease or condition to
153 guide treatment decisions if medical and scientific evidence
154 indicates that the biomarker testing provides clinical utility
155 to the recipient. Such medical and scientific evidence includes,
156 but is not limited to:

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

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

161 3. A national coverage determination made by the Centers
162 for Medicare and Medicaid Services or a local coverage
163 determination made by the Medicare Administrative Contractor; or

164 4. A nationally recognized clinical practice guideline. As
165 used in this subparagraph, the term "nationally recognized
166 clinical practice guideline" means an evidence-based clinical
167 practice guideline developed by independent organizations or
168 medical professional societies using a transparent methodology
169 and reporting structure and with a conflict-of-interest policy.
170 Guidelines developed by such organizations or societies
171 establish standards of care informed by a systematic review of
172 evidence and an assessment of the benefits and costs of
173 alternative care options and include recommendations intended to
174 optimize patient care.

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175 (c) Recipients and participating providers must be provided
176 access to a clear and convenient process to request
177 authorization for biomarker testing as provided under this
178 subsection. Such process must be made readily accessible online
179 to all recipients and participating providers.

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

182 (e) The agency may seek federal approval necessary to
183 implement this subsection.

184 Section 3. Section 409.9745, Florida Statutes, is created
185 to read:

186 409.9745 Managed care plan biomarker testing.—

187 (1) A managed care plan must provide coverage for biomarker
188 testing for recipients, as authorized under s. 409.906, at the
189 same scope, duration, and frequency as the Medicaid program
190 provides for other medically necessary treatments.

191 (2) The managed care plan shall provide recipients and
192 health care providers with access to a clear and convenient
193 process to request authorization for biomarker testing as
194 provided under this section. Such process must be made readily
195 accessible on the managed care plan's website.

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

198 Section 4. The Agency for Health Care Administration is
199 directed to include the rate impact of this act in the
200 applicable Medicaid managed medical assistance program and long-
201 term care managed care program rates that become effective on
202 October 1, 2024.

203 Section 5. This act shall take effect October 1, 2024.