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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/08/2024	.	
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The Committee on Banking and Insurance (Calatayud) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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) As used in this subsection, the term:

1. "Biomarker" means a defined characteristic that is



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11 measured as an indicator of normal biological processes,
12 pathogenic processes, or responses to an exposure or
13 intervention, including therapeutic interventions. The term
14 includes, but is not limited to, molecular, histologic,
15 radiographic, or physiologic characteristics but does not
16 include an assessment of how a patient feels, functions, or
17 survives.

18 2. "Biomarker testing" means an analysis of a patient's
19 tissue, blood, or other biospecimen for the presence of a
20 biomarker. The term includes, but is not limited to, single
21 analyte tests, multiplex panel tests, protein expression, and
22 whole exome, whole genome, and whole transcriptome sequencing
23 performed at a participating in-network laboratory facility that
24 is certified pursuant to the federal Clinical Laboratory
25 Improvement Amendment (CLIA) or that has obtained a CLIA
26 Certificate of Waiver by the United States Food and Drug
27 Administration for the tests.

28 3. "Clinical utility" means the test result provides
29 information that is used in the formulation of a treatment or
30 monitoring strategy that informs a patient's outcome and impacts
31 the clinical decision.

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



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

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

44 3. A national coverage determination made by the Centers
45 for Medicare and Medicaid Services or a local coverage
46 determination made by the Medicare Administrative Contractor; or

47 4. A nationally recognized clinical practice guideline. As
48 used in this subparagraph, the term "nationally recognized
49 clinical practice guideline" means an evidence-based clinical
50 practice guideline developed by independent organizations or
51 medical professional societies using a transparent methodology
52 and reporting structure and with a conflict-of-interest policy.
53 Guidelines developed by such organizations or societies
54 establish standards of care informed by a systematic review of
55 evidence and an assessment of the benefits and costs of
56 alternative care options and include recommendations intended to
57 optimize patient care.

58 (c) Each state group health insurance plan shall provide
59 enrollees and participating providers with a clear and
60 convenient process to request authorization for biomarker
61 testing. Such process must be made readily accessible online to
62 all enrollees and participating providers.

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

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

67 409.906 Optional Medicaid services.—Subject to specific
68 appropriations, the agency may make payments for services which



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69 are optional to the state under Title XIX of the Social Security
70 Act and are furnished by Medicaid providers to recipients who
71 are determined to be eligible on the dates on which the services
72 were provided. Any optional service that is provided shall be
73 provided only when medically necessary and in accordance with
74 state and federal law. Optional services rendered by providers
75 in mobile units to Medicaid recipients may be restricted or
76 prohibited by the agency. Nothing in this section shall be
77 construed to prevent or limit the agency from adjusting fees,
78 reimbursement rates, lengths of stay, number of visits, or
79 number of services, or making any other adjustments necessary to
80 comply with the availability of moneys and any limitations or
81 directions provided for in the General Appropriations Act or
82 chapter 216. If necessary to safeguard the state's systems of
83 providing services to elderly and disabled persons and subject
84 to the notice and review provisions of s. 216.177, the Governor
85 may direct the Agency for Health Care Administration to amend
86 the Medicaid state plan to delete the optional Medicaid service
87 known as "Intermediate Care Facilities for the Developmentally
88 Disabled." Optional services may include:

89 (29) BIOMARKER TESTING SERVICES.—

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

91 1. "Biomarker" means a defined characteristic that is
92 measured as an indicator of normal biological processes,
93 pathogenic processes, or responses to an exposure or
94 intervention, including therapeutic interventions. The term
95 includes, but is not limited to, molecular, histologic,
96 radiographic, or physiologic characteristics but does not
97 include an assessment of how a patient feels, functions, or



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98 survives.

99 2. "Biomarker testing" means an analysis of a patient's
100 tissue, blood, or other biospecimen for the presence of a
101 biomarker. The term includes, but is not limited to, single
102 analyte tests, multiplex panel tests, protein expression, and
103 whole exome, whole genome, and whole transcriptome sequencing
104 performed at a participating in-network laboratory facility that
105 is certified pursuant to the federal Clinical Laboratory
106 Improvement Amendment (CLIA) or that has obtained a CLIA
107 Certificate of Waiver by the United States Food and Drug
108 Administration for the tests.

109 3. "Clinical utility" means the test result provides
110 information that is used in the formulation of a treatment or
111 monitoring strategy that informs a patient's outcome and impacts
112 the clinical decision.

113 (b) The agency may pay for biomarker testing for the
114 purposes of diagnosis, treatment, appropriate management, or
115 ongoing monitoring of a recipient's disease or condition to
116 guide treatment decisions if medical and scientific evidence
117 indicates that the biomarker testing provides clinical utility
118 to the recipient. Such medical and scientific evidence includes,
119 but is not limited to:

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

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

124 3. A national coverage determination made by the Centers
125 for Medicare and Medicaid Services or a local coverage
126 determination made by the Medicare Administrative Contractor; or



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127 4. A nationally recognized clinical practice guideline. As
128 used in this subparagraph, the term "nationally recognized
129 clinical practice guideline" means an evidence-based clinical
130 practice guideline developed by independent organizations or
131 medical professional societies using a transparent methodology
132 and reporting structure and with a conflict-of-interest policy.
133 Guidelines developed by such organizations or societies
134 establish standards of care informed by a systematic review of
135 evidence and an assessment of the benefits and costs of
136 alternative care options and include recommendations intended to
137 optimize patient care.

138 (c) Recipients and participating providers must be provided
139 access to a clear and convenient process to request
140 authorization for biomarker testing as provided under this
141 subsection. Such process must be made readily accessible online
142 to all recipients and participating providers.

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

145 (e) The agency may seek federal approval necessary to
146 implement this subsection.

147 Section 3. Section 409.9745, Florida Statutes, is created
148 to read:

149 409.9745 Managed care plan biomarker testing.—

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

154 (2) The managed care plan shall provide recipients and
155 health care providers with access to a clear and convenient



156 process to request authorization for biomarker testing as
157 provided under this section. Such process must be made readily
158 accessible on the managed care plan's website.

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

161 Section 4. This act shall take effect July 1, 2024.

162
163 ===== T I T L E A M E N D M E N T =====

164 And the title is amended as follows:

165 Delete everything before the enacting clause
166 and insert:

167 A bill to be entitled
168 An act relating to coverage for biomarker testing;
169 amending s. 110.12303, F.S.; defining terms; requiring
170 the Department of Management Services to provide
171 coverage of biomarker testing for specified purposes
172 for state employees' state group health insurance plan
173 policies issued on or after a specified date;
174 specifying circumstances under which such coverage may
175 be provided; requiring state group health insurance
176 plans to provide enrollees and participating providers
177 with a clear and convenient process for authorization
178 requests for biomarker testing; requiring that such
179 process be readily accessible online; providing
180 construction; amending s. 409.906, F.S.; defining
181 terms; authorizing the Agency for Health Care
182 Administration to pay for biomarker testing under the
183 Medicaid program for specified purposes, subject to
184 specific appropriations; specifying circumstances



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185 under which such payments may be made; requiring that
186 Medicaid recipients and participating providers be
187 provided a clear and convenient process for
188 authorization requests for biomarker testing;
189 requiring that such process be readily accessible
190 online; providing construction; authorizing the agency
191 to seek federal approval for biomarker testing
192 payments; creating s. 409.9745, F.S.; requiring
193 managed care plans under contract with the agency in
194 the Medicaid program to provide coverage for biomarker
195 testing for Medicaid recipients in a certain manner;
196 requiring managed care plans to provide Medicaid
197 recipients and health care providers with a clear and
198 convenient process for authorization requests for
199 biomarker testing; requiring that such process be
200 readily accessible on the managed care plan's website;
201 providing construction; providing an effective date.