

By the Committee on Banking and Insurance; and Senator Calatayud

597-03029-24

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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; providing an effective date.  
36

37 Be It Enacted by the Legislature of the State of Florida:  
38

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

41 110.12303 State group insurance program; additional  
42 benefits; price transparency program; reporting.—

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

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

52 2. "Biomarker testing" means an analysis of a patient's  
53 tissue, blood, or other biospecimen for the presence of a  
54 biomarker. The term includes, but is not limited to, single  
55 analyte tests, multiplex panel tests, protein expression, and  
56 whole exome, whole genome, and whole transcriptome sequencing  
57 performed at a participating in-network laboratory facility that  
58 is certified pursuant to the federal Clinical Laboratory

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59 Improvement Amendment (CLIA) or that has obtained a CLIA  
60 Certificate of Waiver by the United States Food and Drug  
61 Administration for the tests.

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

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

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

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

78 3. A national coverage determination made by the Centers  
79 for Medicare and Medicaid Services or a local coverage  
80 determination made by the Medicare Administrative Contractor; or

81 4. A nationally recognized clinical practice guideline. As  
82 used in this subparagraph, the term "nationally recognized  
83 clinical practice guideline" means an evidence-based clinical  
84 practice guideline developed by independent organizations or  
85 medical professional societies using a transparent methodology  
86 and reporting structure and with a conflict-of-interest policy.  
87 Guidelines developed by such organizations or societies

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88 establish standards of care informed by a systematic review of  
89 evidence and an assessment of the benefits and costs of  
90 alternative care options and include recommendations intended to  
91 optimize patient care.

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

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

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

101 409.906 Optional Medicaid services.—Subject to specific  
102 appropriations, the agency may make payments for services which  
103 are optional to the state under Title XIX of the Social Security  
104 Act and are furnished by Medicaid providers to recipients who  
105 are determined to be eligible on the dates on which the services  
106 were provided. Any optional service that is provided shall be  
107 provided only when medically necessary and in accordance with  
108 state and federal law. Optional services rendered by providers  
109 in mobile units to Medicaid recipients may be restricted or  
110 prohibited by the agency. Nothing in this section shall be  
111 construed to prevent or limit the agency from adjusting fees,  
112 reimbursement rates, lengths of stay, number of visits, or  
113 number of services, or making any other adjustments necessary to  
114 comply with the availability of moneys and any limitations or  
115 directions provided for in the General Appropriations Act or  
116 chapter 216. If necessary to safeguard the state's systems of

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117 providing services to elderly and disabled persons and subject  
118 to the notice and review provisions of s. 216.177, the Governor  
119 may direct the Agency for Health Care Administration to amend  
120 the Medicaid state plan to delete the optional Medicaid service  
121 known as "Intermediate Care Facilities for the Developmentally  
122 Disabled." Optional services may include:

123 (29) BIOMARKER TESTING SERVICES.-

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

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

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

143 3. "Clinical utility" means the test result provides  
144 information that is used in the formulation of a treatment or  
145 monitoring strategy that informs a patient's outcome and impacts

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146 the clinical decision.

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

154 1. A labeled indication for a test approved or cleared by  
155 the Unites States Food and Drug Administration;

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

158 3. A national coverage determination made by the Centers  
159 for Medicare and Medicaid Services or a local coverage  
160 determination made by the Medicare Administrative Contractor; or

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

172 (c) Recipients and participating providers must be provided  
173 access to a clear and convenient process to request  
174 authorization for biomarker testing as provided under this

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175 subsection. Such process must be made readily accessible online  
176 to all recipients and participating providers.

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

179 (e) The agency may seek federal approval necessary to  
180 implement this subsection.

181 Section 3. Section 409.9745, Florida Statutes, is created  
182 to read:

183 409.9745 Managed care plan biomarker testing.-

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

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

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

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