

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	<u> </u>	(Y/N)
ADOPTED AS AMENDED	<u> </u>	(Y/N)
ADOPTED W/O OBJECTION	<u> </u>	(Y/N)
FAILED TO ADOPT	<u> </u>	(Y/N)
WITHDRAWN	<u> </u>	(Y/N)
OTHER	<u> </u>	

1 Committee/Subcommittee hearing bill: Select Committee on Health
 2 Innovation

3 Representative Gonzalez Pittman offered the following:

4

5 **Amendment (with title amendment)**

6 Remove lines 131-328 and insert:

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

9 110.12303 State group insurance program; additional
 10 benefits; price transparency program; reporting.—

11 (5) Coverage for biomarking testing.

12 (a) Effective for state group health insurance plan
 13 policies issued on or after January 1, 2025, the department
 14 shall provide coverage of biomarker testing for the purposes of
 15 diagnosis, treatment, appropriate management, or ongoing
 16 monitoring of a enrollee's disease or condition to guide

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17 treatment decisions if medical and scientific evidence indicates
18 that the biomarker testing provides clinical utility to the
19 enrollee. Such medical and scientific evidence includes, but is
20 not limited to:

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

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

25 3. A national coverage determination made by the Centers
26 for Medicare and Medicaid Services or a local coverage
27 determination made by the Medicare Administrative Contractor; or

28 4. A nationally recognized clinical practice guideline. As
29 used in this subparagraph, the term "nationally recognized
30 clinical practice guideline" means an evidence-based clinical
31 practice guideline developed by independent organizations or
32 medical professional societies using a transparent methodology
33 and reporting structure and with a conflict-of-interest policy.
34 Guidelines developed by such organizations or societies
35 establish standards of care informed by a systematic review of
36 evidence and an assessment of the benefits and costs of
37 alternative care options and include recommendations intended to
38 optimize patient care.

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

40 1. "Biomarker" means a defined characteristic that is
41 measured as an indicator of normal biological processes,

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42 pathogenic processes, or responses to an exposure or
43 intervention, including therapeutic interventions. The term
44 includes, but is not limited to, molecular, histologic,
45 radiographic, or physiologic characteristics but does not
46 include an assessment of how a patient feels, functions, or
47 survives.

48 2. "Biomarker testing" means an analysis of a patient's
49 tissue, blood, or other biospecimen for the presence of a
50 biomarker. The term includes, but is not limited to, single
51 analyte tests, multiplex panel tests, protein expression, and
52 whole exome, whole genome, and whole transcriptome sequencing
53 performed at a participating in-network laboratory facility that
54 is certified pursuant to the federal Clinical Laboratory
55 Improvement Amendment (CLIA) or that has obtained a CLIA
56 Certificate of Waiver by the United States Food and Drug
57 Administration for the tests.

58 3. "Clinical utility" means the test result provides
59 information that is used in the formulation of a treatment or
60 monitoring strategy that informs a patient's outcome and impacts
61 the clinical decision.

62 (c) Each contracted preferred provider organization and
63 health maintenance organization shall provide a clear and
64 convenient process for providers to request authorization for
65 biomarker testing. Such process shall be made readily accessible
66 to all enrollees and participating providers online.

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

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T I T L E A M E N D M E N T

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Remove lines 19-29 and insert:

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biomarker testing; providing construction; amending s.

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110.12303, F.S.; requiring the state employee health plan to

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provide coverage for biomarker testing for certain purposes;

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specifying circumstances under which such coverage may be

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provided; requiring a clear, readily accessible, and convenient

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process for authorization requests for biomarker testing;

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providing construction; providing