

SENATE BILL NO. 104

BY SENATORS STINE, DUPLESSIS, FESI, JACKSON, ROBERT MILLS, PEACOCK,  
SMITH AND TALBOT

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

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AN ACT

To enact R.S. 22:1028.5, relative to health insurance coverage; to require health insurance coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition; to provide coverage requirements; to provide for definitions; to provide for applicability; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1028.5 is hereby enacted to read as follows:

**§1028.5. Required coverage for biomarker testing**

**A. The legislature hereby finds that medical advances in genomic testing for diseases and other medical conditions including but not limited to biomarker testing can identify characteristics of disease or any other medical condition more accurately and greatly improve the individual's outcome by providing personalized care.**

**B.(1) Any health coverage plan renewed, delivered, or issued for delivery in this state shall include coverage of biomarker testing.**

**(2) The coverage provided in this Section may be subject to annual deductibles, coinsurance, and copayment provisions as are consistent with those established under the health coverage plan. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test provides clinical utility as demonstrated by medical and scientific evidence, including any one of the following items:**

**(a) Labeled indications for diagnostic tests approved or cleared by the**

1 United States Food and Drug Administration or indicated diagnostic tests for  
2 a drug approved by the United States Food and Drug Administration.

3 (b) Warnings and precautions listed on a United States Food and Drug  
4 Administration approved drug label.

5 (c) National Coverage Determinations of the Centers for Medicare and  
6 Medicaid Services or Local Coverage Determinations of Medicare  
7 Administrative Contractors.

8 (d) Nationally recognized clinical practice guidelines.

9 (3) This Section does not require a health coverage plan to cover  
10 biomarker testing for screening purposes.

11 C. The individual and healthcare provider shall have access to a clear,  
12 readily accessible, and convenient process to request an exception to a coverage  
13 policy or adverse utilization review determination of a health coverage plan.  
14 The process shall be made readily accessible on the health coverage plan's  
15 website or be clearly outlined in the notification of adverse determination.

16 D. A health coverage plan shall ensure that the coverage prescribed in  
17 Subsection B of this Section is provided in a manner that limits disruptions in  
18 care, including the need for multiple biopsies or biospecimen samples.

19 E. As used in this Section, the following definitions apply unless the  
20 context indicates otherwise:

21 (1) "Biomarker" means a characteristic that is objectively measured and  
22 evaluated as an indicator of normal biological processes, pathogenic processes,  
23 or pharmacologic responses to a specific therapeutic intervention, including  
24 known gene-drug interactions for medication being considered for use or  
25 currently administered. A "biomarker" includes but is not limited to gene  
26 mutations, characteristics of genes, or protein expression.

27 (2) "Biomarker testing" means the analysis of a patient's tissue, blood,  
28 or other biospecimen for the presence of a biomarker. "Biomarker testing"  
29 includes but is not limited to single-analyte tests, multi-plex panel tests, protein  
30 expression, whole exome, whole genome, and whole transcriptome sequencing.

1                   **(3)(a) "Clinical utility" means a test result to provide information that**  
2                   **is used in the formulation of a treatment or monitoring strategy that informs a**  
3                   **patient's outcome and impacts the clinical decision.**

4                   **(b) The most appropriate test may include both information that is**  
5                   **actionable and information that cannot be immediately used in the formulation**  
6                   **of a clinical decision.**

7                   **(4) "Health coverage plan" means any hospital, health, or medical**  
8                   **expense insurance policy, hospital or medical service contract, employee welfare**  
9                   **benefit plan, contract, or other agreement with a health maintenance**  
10                  **organization or a preferred provider organization, health and accident**  
11                  **insurance policy, or any other insurance contract of this type in this state,**  
12                  **including a group insurance plan or self-insurance plan, and the office of group**  
13                  **benefits. "Health coverage plan" does not include a plan providing coverage for**  
14                  **excepted benefits defined in R.S. 22:1061, limited benefit health insurance plans,**  
15                  **or short-term policies that have a term of less than twelve months.**

16                  **(5) "Nationally recognized clinical practice guidelines" means**  
17                  **evidence-based clinical guidelines developed by independent organizations or**  
18                  **medical professional societies utilizing a transparent methodology and reporting**  
19                  **structure and with a conflict-of-interest policy. The guidelines establish**  
20                  **standards of care informed by a systematic review of evidence and an**  
21                  **assessment of the benefits and risks of alternative care options and include**  
22                  **recommendations intended to optimize patient care.**

23                  Section 2. The provisions of this Act shall apply to any new policy, contract,  
24                  program, or health coverage plan issued on or after the January first immediately following  
25                  the effective date of this Act. Any policy, contract, or health coverage plan in effect prior to  
26                  the effective date of this Act shall convert to conform to the provisions of this Act on or  
27                  before the renewal date, but no later than the first January first that is at least one year after  
28                  the effective date of this Act.

29                  Section 3.(A) The provisions of Sections 1 and 2 of this Act shall become effective  
30                  when an Act of the Louisiana Legislature containing a specific appropriation of monies for

1 the implementation of the provisions of this Act becomes effective.

2 (B) The provisions of this Section shall become effective upon signature by the  
3 governor or, if not signed by the governor, upon expiration of the time for bills to become  
4 law without signature by the governor, as provided by Article III, Section 18 of the  
5 Constitution of Louisiana. If vetoed by the governor and subsequently approved by the  
6 legislature, the provisions of this Section shall become effective on the day following such  
approval.

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PRESIDENT OF THE SENATE

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: \_\_\_\_\_