SLS 23RS-345 **ENGROSSED**

2023 Regular Session

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.

GENETICS. Provides for health insurance coverage of genetic testing for diseases and other medical conditions. (8/1/23)

AN ACT

To enact R.S. 22:1028.5, relative to health coverage insurance; to require health insurance coverage for biomarker testing shall be covered 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 the definition of health coverage plan; to provide for definitions; 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 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 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 is supported by medical and scientific evidence, including any one of the following items:

(a) Labeled indications for diagnostic tests approved or cleared by the United States Food and Drug Administration or indicated diagnostic tests for a drug approved by the United States Food and Drug Administration.

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

(c) Centers for Medicare and Medicaid Services National Coverage Determination or a Medicare Administrative Contractor Local Coverage Determination.

(d) Nationally recognized clinical practice guidelines and consensus statements.

C. The individual and healthcare provider shall have access to a clear, readily accessible, and convenient processes to request an exception to a coverage policy or adverse utilization review determination of a health coverage plan. The process shall be made readily accessible on the health coverage plan's website.

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

E. For purposes of this Section, "health coverage plan" means any hospital, health, or medical expense insurance policy, hospital or medical service contract, employee welfare benefit plan, contract, or other agreement with a health maintenance organization or a preferred provider organization, health and accident insurance policy, or any other insurance contract of this type in this state, including a group insurance plan or self-insurance plan, and the office of group benefits. "Health coverage plan" does not include a plan

providing coverage for excepted benefits defined in R.S. 22:1061, limited benefit health insurance plans, or short-term policies that have a term of less than twelve months.

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

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

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

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict-of-interest policy. The statements are aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

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

The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Beth O'Quin.

DIGEST

SB 104 Engrossed 2023 Regular Session Stine

Proposed law requires any health coverage plan renewed, delivered, or issued for delivery, in this state to include coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence, including any one of the following:

(1) Labeled indications for diagnostic tests approved or cleared by the United States Food and Drug Administration (FDA) or indicated diagnostic tests for a drug approved by the FDA.

(2) Warnings and precautions listed on a FDA approved drug label.

(3) Centers for Medicare and Medicaid Services National Coverage Determination or a Medicare Administrative Contractor Local Coverage Determination.

(4) Nationally recognized clinical practice guidelines and consensus statements.

Proposed law authorizes the coverage is subject to annual deductibles, coinsurance, and copayment provisions as are consistent with those established under the health plan.

Proposed law requires individuals and healthcare providers have access to clear, readily accessible, convenient processes to request exceptions to a coverage policy or adverse determination review determination of a health coverage plan. Requires the process to be included on a health coverage plan's website.

Proposed law requires a health coverage plan to ensure coverage under proposed law is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

Proposed law defines biomarker, biomarker testing, consensus statements, health coverage plans, and Nationally recognized clinical practice guidelines.

Effective August 1, 2023.

(Adds R.S. 22:1028.5)

Summary of Amendments Adopted by Senate

Committee Amendments Proposed by Senate Committee on Insurance to the original bill

1. Provides that tests are diagnostic tests.

2. Makes technical changes.