By: Bonnen H.B. No. 3188

A BILL TO BE ENTITLED

AN ACT

relating to health benefit plan coverage for certain biomarker testing.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle E, Title 8, Insurance Code, is amended by adding Chapter 1372 to read as follows:

CHAPTER 1372. COVERAGE FOR BIOMARKER TESTING

Sec. 1372.001. DEFINITIONS. In this chapter:

(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. The term includes:

(A) gene mutations; and

(B) protein expression.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes:

(A) single-analyte tests;

(B) multiplex panel tests; and

(C) whole genome sequencing.

(3) "Consensus statements" means statements that:

(A) address specific clinical circumstances based on the best available evidence for the purpose of optimizing

clinical care outcomes; and

(B) are developed by an independent, multidisciplinary panel of experts that uses a transparent methodology and reporting structure and is subject to a conflict of interest policy.

(4) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) establish a standard of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options;

(B) include recommendations intended to optimize patient care; and

(C) are developed by an independent organization or medical professional society that uses a transparent methodology and reporting structure and is subject to a conflict of interest policy.

Sec. 1372.002. APPLICABILITY OF CHAPTER. (a) This chapter applies only to a health benefit plan that provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:

(1) an insurance company;

(2) a group hospital service corporation operating under Chapter 842;

(3) a health maintenance organization operating under Chapter 843;

(4) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844;

(5) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846;

(6) a stipulated premium company operating under Chapter 884;

(7) a fraternal benefit society operating under Chapter 885;

(8) a Lloyd's plan operating under Chapter 941; or

(9) an exchange operating under Chapter 942.

(b) Notwithstanding any other law, this chapter applies to:

(1) a small employer health benefit plan subject to Chapter 1501, including coverage provided through a health group cooperative under Subchapter B of that chapter;

(2) a standard health benefit plan issued under Chapter 1507;

(3) a basic coverage plan under Chapter 1551;

(4) a basic plan under Chapter 1575;

(5) a primary care coverage plan under Chapter 1579;

(6) a plan providing basic coverage under Chapter 1601;

(7) health benefits provided by or through a church benefits board under Subchapter I, Chapter 22, Business Organizations Code;

(8) the state Medicaid program, including the Medicaid

managed care program operated under Chapter 533, Government Code;

(9) the child health plan program under Chapter 62, Health and Safety Code;

(10) a regional or local health care program operated under Section 75.104, Health and Safety Code;

(11) a self-funded health benefit plan sponsored by a professional employer organization under Chapter 91, Labor Code;

(12) county employee group health benefits provided under Chapter 157, Local Government Code; and

(13) health and accident coverage provided by a risk pool created under Chapter 172, Local Government Code.

Sec. 1372.003. COVERAGE REQUIRED. (a) Subject to Subsection (b), a health benefit plan must provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment when the test is supported by medical and scientific evidence, including:

(1) a labeled indication for a test approved or cleared by the United States Food and Drug Administration;

(2) an indicated test for a drug approved by the United States Food and Drug Administration;

(3) a national coverage determination made by the Centers for Medicare and Medicaid Services or a local coverage determination made by a Medicare administrative contractor;

(4) nationally recognized clinical practice guidelines; or

(5) consensus statements.

(b) A health benefit plan issuer must provide coverage under Subsection (a) only when use of biomarker testing provides clinical utility because use of the test for the condition:

(1) is evidence-based;

(2) is scientifically valid;

(3) is outcome focused; and

(4) predominately addresses the acute issue for which the test is being ordered, except that a test may include some information that cannot be immediately used in the formulation of a clinical decision.

(c) A health benefit plan must provide coverage under Subsection (a) in a manner that limits disruptions in care, including limiting the number of biopsies and biospecimen samples.

SECTION 2. If before implementing any provision of this Act a state agency determines that a waiver or authorization from a federal agency is necessary for implementation of that provision, the agency affected by the provision shall request the waiver or authorization and may delay implementing that provision until the waiver or authorization is granted.

SECTION 3. The change in law made by this Act applies only to a health benefit plan that is delivered, issued for delivery, or renewed on or after January 1, 2024.

SECTION 4. This Act takes effect September 1, 2023.