By: Huffman, et al.

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## A BILL TO BE ENTITLED

1	AN ACT
2	relating to health benefit plan coverage for certain biomarker
3	testing.
4	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
5	SECTION 1. Subtitle E, Title 8, Insurance Code, is amended
6	by adding Chapter 1372 to read as follows:
7	CHAPTER 1372. COVERAGE FOR BIOMARKER TESTING
8	Sec. 1372.001. DEFINITIONS. In this chapter:
9	(1) "Biomarker" means a characteristic that is
10	objectively measured and evaluated as an indicator of normal
11	biological processes, pathogenic processes, or pharmacologic
12	responses to a specific therapeutic intervention. The term
13	includes:
14	(A) gene mutations; and
15	(B) protein expression.
16	(2) "Biomarker testing" means the analysis of a
17	patient's tissue, blood, or other biospecimen for the presence of a
18	biomarker. The term includes:
19	(A) single-analyte tests;
20	(B) multiplex panel tests; and
21	(C) whole genome sequencing.
22	(3) "Consensus statements" means statements that:
23	(A) address specific clinical circumstances
24	based on the best available evidence for the purpose of optimizing

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1	clinical care outcomes; and
2	(B) are developed by an independent,
3	multidisciplinary panel of experts that uses a transparent
4	methodology and reporting structure and is subject to a conflict of
5	interest policy.
6	(4) "Nationally recognized clinical practice
7	guidelines" means evidence-based clinical practice guidelines
8	that:
9	(A) establish a standard of care informed by a
10	systematic review of evidence and an assessment of the benefits and
11	costs of alternative care options;
12	(B) include recommendations intended to optimize
13	patient care; and
14	(C) are developed by an independent organization
15	or medical professional society that uses a transparent methodology
16	and reporting structure and is subject to a conflict of interest
17	policy.
18	Sec. 1372.002. APPLICABILITY OF CHAPTER. (a) This chapter
19	applies only to a health benefit plan that provides benefits for
20	medical or surgical expenses incurred as a result of a health
21	condition, accident, or sickness, including an individual, group,
22	blanket, or franchise insurance policy or insurance agreement, a
23	group hospital service contract, or an individual or group evidence
24	of coverage or similar coverage document that is offered by:
25	(1) an insurance company;
26	(2) a group hospital service corporation operating
27	under Chapter 842;

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1	(3) a health maintenance organization operating under
2	Chapter 843;
3	(4) an approved nonprofit health corporation that
4	holds a certificate of authority under Chapter 844;
5	(5) a multiple employer welfare arrangement that holds
6	a certificate of authority under Chapter 846;
7	(6) a stipulated premium company operating under
8	Chapter 884;
9	(7) a fraternal benefit society operating under
10	Chapter 885;
11	(8) a Lloyd's plan operating under Chapter 941; or
12	(9) an exchange operating under Chapter 942.
13	(b) Notwithstanding any other law, this chapter applies to:
14	(1) a small employer health benefit plan subject to
15	Chapter 1501, including coverage provided through a health group
16	cooperative under Subchapter B of that chapter;
17	(2) a standard health benefit plan issued under
18	Chapter 1507;
19	(3) a basic coverage plan under Chapter 1551;
20	(4) a basic plan under Chapter 1575;
21	(5) a primary care coverage plan under Chapter 1579;
22	(6) a plan providing basic coverage under Chapter
23	<u>1601;</u>
24	(7) the state Medicaid program, including the Medicaid
25	managed care program operated under Chapter 533, Government Code;
26	(8) the child health plan program under Chapter 62,
27	Health and Safety Code; and

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1	(9) a self-funded health benefit plan sponsored by a
2	professional employer organization under Chapter 91, Labor Code.
3	Sec. 1372.003. COVERAGE REQUIRED. (a) Subject to
4	Subsection (b), a health benefit plan must provide coverage for
5	biomarker testing for the purpose of diagnosis, treatment,
6	appropriate management, or ongoing monitoring of an enrollee's
7	disease or condition to guide treatment when the test is supported
8	by the following kinds of medical and scientific evidence:
9	(1) a labeled indication for a test approved or
10	cleared by the United States Food and Drug Administration;
11	(2) an indicated test for a drug approved by the United
12	States Food and Drug Administration;
13	(3) a national coverage determination made by the
14	Centers for Medicare and Medicaid Services or a local coverage
15	determination made by a Medicare administrative contractor;
16	(4) nationally recognized clinical practice
17	guidelines; or
18	(5) consensus statements.
19	(b) A health benefit plan issuer must provide coverage under
20	Subsection (a) only when use of biomarker testing provides clinical
21	utility because use of the test for the condition:
22	(1) is evidence-based;
23	(2) is scientifically valid based on the medical and
24	scientific evidence described by Subsection (a);
25	(3) informs a patient's outcome and a provider's
26	clinical decision; and
27	(4) predominately addresses the acute or chronic issue

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1 for which the test is being ordered, except that a test may include 2 some information that cannot be immediately used in the formulation 3 of a clinical decision.

4 (c) A health benefit plan must provide coverage under
5 Subsection (a) in a manner that limits disruptions in care,
6 including limiting the number of biopsies and biospecimen samples.
7 SECTION 2. If before implementing any provision of this Act

8 a state agency determines that a waiver or authorization from a 9 federal agency is necessary for implementation of that provision, 10 the agency affected by the provision shall request the waiver or 11 authorization and may delay implementing that provision until the 12 waiver or authorization is granted.

13 SECTION 3. The change in law made by this Act applies only 14 to a health benefit plan that is delivered, issued for delivery, or 15 renewed on or after January 1, 2024.

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

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