By: Huffman, Gutierrez

(In the Senate - Filed February 16, 2023; March 3, 2023, read first time and referred to Committee on Health & Human Services; April 3, 2023, reported adversely, with favorable Committee Substitute by the following vote: Yeas 8, Nays 1; 1-2 1-3 1-4 1-5 1-6 April 3, 2023, sent to printer.) COMMITTEE VOTE 1-7 1-8 Absent **PNV** Yea Nay 1-9 Kolkhorst Χ 1-10 1-11 Perry Blanco X 1-12 Hall 1-13 X Hancock 1-14 Hughes Χ 1**-**15 1**-**16 LaMantia Miles 1-17 Sparks Χ 1-18 COMMITTEE SUBSTITUTE FOR S.B. No. 989 By: Hall 1-19 A BILL TO BE ENTITLED 1-20 AN ACT 1-21 relating to health benefit plan coverage for certain biomarker 1-22 testing. 1-23 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: 1-24 SECTION 1. Subtitle E, Title 8, Insurance Code, is amended 1-25 by adding Chapter 1372 to read as follows: CHAPTER 1372. COVERAGE FOR BIOMARKER TESTING 1372.001. DEFINITIONS. In this chapter:

(1) "Biomarker" means a characteristic 1-26 1-27 Sec 1-28 objectively measured and evaluated as an indicator of normal 1-29 processes, pathogenic processes, or pharmacologic to a specific therapeutic intervention. The term 1-30 biological 1-31 responses 1-32 includes: 1-33 (A) gene mutations; and 1-34 (B) protein expression. (2) "Biomarker testing" means the analysis of patient's tissue, blood, or other biospecimen for the presence of biomarker. The term includes: 1-35 1-36 1-37 (A) single-analyte tests; 1-38 1-39 (B) multiplex panel tests; and (C) whole genome sequencing.
"Consensus statements" means statements that:

(A) address specific clinical circumstances 1-40 1-41 1-42 based on the best available evidence for the purpose of optimizing 1-43 1-44 clinical care outcomes; and bу independent, 1-45 (B) are developed an of 1-46 multidisciplinary panel experts that uses а transparent methodology and reporting structure and is subject to a conflict of 1-47 interest policy. (4) "Nationally 1-48 1-49 (4) "Nationally recognized clinical practice means evidence-based clinical practice guidelines guidelines" 1-50 1-51 that: 1-52 (A) establish a standard of care informed by a 1-53 systematic review of evidence and an assessment of the benefits and 1-54 costs of alternative care options; 1-55 (B) include recommendations intended to optimize 1-56 patient care; and 1-57 (C) are developed by an independent organization 1-58 or medical professional society that uses a transparent methodology and reporting structure and is subject to a conflict of interest 1-59

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policy.

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C.S.S.B. No. 989
                                                                (a) This chapter
                                APPLICABILITY OF CHAPTER.
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                    1372.002.
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      applies only to a health benefit plan that provides benefits for
      medical or surgical expenses incurred as a result of a health
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       condition, accident, or sickness, including an individual, group,
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       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:
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                          an insurance company;
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                    (2)
                          a group hospital service corporation operating
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      under Chapter 842;
(3) a
                          a health maintenance organization operating under
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      Chapter 843;
                              approved nonprofit health corporation that
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                    (4)
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      holds a certificate of authority under Chapter 844;
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                          a multiple employer welfare arrangement that holds
       a certificate of
                         authority under Chapter 846;
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                    (6)
                          a__
                             stipulated premium company
                                                                operating under
      Chapter 884;
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                    (7)
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                          а
                             fraternal benefit society operating under
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      Chapter 885;
                    (8)
                          a Lloyd's plan operating under Chapter 941; or
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                    (9) an exchange operating under Chapter 942.
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                    Notwithstanding any other law, this chapter applies to:
                    (1) a small employer health benefit plan subject to
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       Cha<u>pter 1501,</u>
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       Chapter 1501, including coverage provided through a health group cooperative under Subchapter B of that chapter;
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                    (2) a standard health benefit plan issued under
      Chapter 1507;
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                    (3)
                          a basic coverage plan under Chapter 1551;
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                    (4)
                          a basic plan under Chapter 1575;
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                    (5)
                          a primary care coverage plan under Chapter 1579;
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                    (6)
                          a plan providing basic coverage under Chapter
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      1601;
      (7) the state Medicaid program, including the Medicaid managed care program operated under Chapter 533, Government Code;

(8) the child health plan program under Chapter 62,
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      Health and Safety Code; and
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                    (9)
                         a self-funded health benefit plan sponsored by a
      professional employer organization under Chapter 91, Labor Code.
Sec. 1372.003. COVERAGE REQUIRED. (a) Subject
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       Subsection (b), a health benefit plan must
                                                          provide coverage for
                  testing for the purpose of diagnosis, treatment,
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      biomarker
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       appropriate management, or ongoing monitoring of an enrollee's
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       disease or condition to guide treatment when the test is supported
                  and scientific evidence, including:
(1) a labeled indication for a
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       by medical
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                                                              test
                                                                     approved or
      cleared by the United States Food and Drug Administration;
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                    (2) an indicated test for a drug approved by the United
      States Food and Drug Administration;
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                          a national
                (3) a national coverage determination made by the for Medicare and Medicaid Services or a local coverage
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      determination made by a Medicare administrative contractor;
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                                          recognized clinical
                    (4)
                         nationally
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       guidelines; or
                    (5) consensus statements.
A health benefit plan issuer must provide coverage under
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       Subsection (a) only when use of biomarker testing provides clinical
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      utility because use of the test for the condition:
                         is evidence-based;
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                    (1)
                          is scientifically valid; is outcome focused; and
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                    (3)
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                    (4)
                          predominately addresses the acute issue for which
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       the test is being ordered, except that a test may include some
       information that cannot be immediately used in the formulation of a
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       clinical decision.
       (c) A health benefit plan must provide coverage under Subsection (a) in a manner that limits disruptions in care,
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       including limiting the number of biopsies and biospecimen samples.
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              SECTION 2. If before implementing any provision of this Act
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C.S.S.B. No. 989

a state agency determines that a waiver or authorization from a federal agency is necessary for implementation of that provision, 3-1 3-2 the agency affected by the provision shall request the waiver or authorization and may delay implementing that provision until the 3**-**3 3-4 3**-**5 3**-**6

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.

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