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## A BILL TO BE ENTITLED

1	AN ACT
2	relating to the use of clinical decision support software and
3	laboratory benefits management programs in connection with the
4	provision of clinical laboratory services to certain managed care
5	plan enrollees.
6	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
7	SECTION 1. Chapter 1451, Insurance Code, is amended by
8	adding Subchapter L to read as follows:
9	SUBCHAPTER L. CLINICAL LABORATORY SERVICES
10	Sec. 1451.551. DEFINITIONS. In this subchapter:
11	(1) "Clinical decision support software" means
12	computer software that compares patient characteristics to a
13	database of clinical knowledge to produce patient-specific
14	assessments or recommendations to assist a physician or health care
15	provider in making clinical decisions.
16	(2) "Clinical laboratory service" means the
17	examination of a specimen taken from a human body ordered by a
18	physician or health care provider for use in the diagnosis,
19	prevention, or treatment of a disease or the identification or
20	assessment of a medical or physical condition.

managed care plan.

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test of a patient specimen analyzing multiple biomarkers of

(3) "Enrollee" means an individual enrolled in a

(4) "Esoteric molecular and genomic testing" means any

deoxyribonucleic acid, ribonucleic acid, or proteins using a unique 1 algorithm to yield a patient-specific prognosis or diagnosis. 2 (5) "Laboratory benefits management program" means a 3 managed care plan issuer protocol or program administered by the 4 5 managed care plan issuer or an entity under contract with the managed care plan issuer that directs or limits decision making of a 6 7 physician or health care provider authorized to order clinical laboratory services. The term includes a requirement for a 8 physician or health care provider to provide advance notice of an 9 10 order for clinical laboratory services. (6) "Managed care plan" means a health benefit plan 11 12 under which health care services are provided to enrollees through contracts with physicians or health care providers and that 13 requires enrollees to use participating providers or that provides 14 15 a different level of coverage for enrollees who use participating providers. The term includes a health benefit plan issued by: 16 17 (A) a health maintenance organization; (B) a preferred or exclusive provider benefit 18 19 plan issuer; or (C) any other entity that issues a health benefit 20 plan described by this subdivision, including an insurance company. 21 (7) "National medical consensus guidelines" means 22 applicable generally accepted practice guidelines that are: 23 24 (A) supported by peer-reviewed medical 25 literature; and 26 (B) promulgated by the federal government or by a

national professional medical society, board, or association.

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- 1 (8) "Participating provider" means a physician or
- 2 health care provider who has contracted with a managed care plan
- 3 issuer to provide services to enrollees.
- 4 (9) "Physician" means a person licensed to practice
- 5 medicine in this state.
- 6 Sec. 1451.552. CERTAIN REQUIREMENTS FOR CLINICAL
- 7 LABORATORY SERVICES PROHIBITED; EXCEPTION. (a) Except as provided
- 8 by Subsection (d), a managed care plan issuer may not require the
- 9 use of clinical decision support software or a laboratory benefits
- 10 management program by an enrollee's physician or health care
- 11 provider before, at the time, or after the physician or health care
- 12 provider orders a clinical laboratory service for the enrollee.
- 13 (b) A managed care plan issuer may not direct or limit the
- 14 decision making of an enrollee's physician or health care provider
- 15 relating to the referral of a patient specimen to a laboratory in
- 16 the managed care plan network or a network otherwise designated by
- 17 the managed care plan issuer.
- 18 (c) A managed care plan issuer may not limit, reduce, or
- 19 deny payment for a clinical laboratory service based on whether the
- 20 ordering physician or health care provider uses clinical decision
- 21 support software or a laboratory benefits management program.
- 22 (d) Subsection (a) does not apply to an order for a clinical
- 23 laboratory service if the specimen is not obtained in a hospital or
- 24 ambulatory surgical center and:
- 25 (1) the order is for esoteric molecular and genomic
- 26 testing; or
- 27 (2) there are national medical consensus guidelines

- 1 available for the clinical laboratory service ordered.
- 2 Sec. 1451.553. CERTAIN REQUIREMENTS FOR SECOND OPINION
- 3 PROHIBITED. A managed care plan issuer may not routinely require a
- 4 second opinion of a pathologist's finding from another pathologist
- 5 unless the second opinion is medically warranted based on the
- 6 specific clinical presentation of the enrollee or other clinical
- 7 factors relevant to the enrollee.
- 8 Sec. 1451.554. CLINICAL DECISION SUPPORT SOFTWARE AND
- 9 LABORATORY BENEFITS MANAGEMENT PROGRAM REQUIREMENTS. (a) A
- 10 managed care plan issuer may only use clinical decision support
- 11 software or a laboratory benefits management program that:
- 12 (1) is transparently based on published,
- 13 peer-reviewed medical literature;
- 14 (2) is subject to timely and routine updates based on
- 15 national medical consensus guidelines and the most current medical
- 16 knowledge; and
- 17 (3) may be immediately overridden by a physician based
- 18 on the physician's medical judgment.
- 19 (b) A managed care plan issuer may not use a laboratory
- 20 benefits management program that is administered, created, or owned
- 21 by an individual or entity with an interest in a clinical laboratory
- 22 <u>in the managed care plan network.</u>
- 23 <u>Sec. 1451.555. SUPERVISION BY COMPARABLE PROFESSIONAL</u>
- 24 REQUIRED. A managed care plan issuer may only use clinical decision
- 25 support software, a laboratory benefits management program, or a
- 26 prior authorization protocol for clinical laboratory services that
- 27 is supervised by a physician of the same or a similar specialty as

- 1 the ordering physician or health care provider.
- 2 Sec. 1451.556. APPLICABILITY OF SUBCHAPTER TO ENTITIES
- 3 CONTRACTING WITH MANAGED CARE PLAN ISSUER. This subchapter applies
- 4 to a person with whom a managed care plan issuer contracts to:
- 5 (1) manage or administer benefits for clinical
- 6 laboratory services;
- 7 (2) process or pay claims;
- 8 (3) obtain the services of physicians or other health
- 9 care providers to provide health care services to enrollees; or
- 10 (4) issue verifications or prior authorizations.
- Sec. 1451.557. CONSTRUCTION OF SUBCHAPTER. This subchapter
- 12 may not be construed to regulate the implementation or
- 13 administration of clinical decision support software, a laboratory
- 14 benefits management program, or a prior authorization protocol by
- 15 <u>an entity, including a health care entity, that is not acting on</u>
- 16 behalf of or at the direction of a managed care plan issuer in
- 17 adopting the software, program, or protocol.
- 18 SECTION 2. Subchapter L, Chapter 1451, Insurance Code, as
- 19 added by this Act, applies only to a contract between a managed care
- 20 plan issuer and a physician or health care provider that is entered
- 21 into or renewed on or after the effective date of this Act. A
- 22 contract entered into or renewed before the effective date of this
- 23 Act is governed by the law as it existed immediately before the
- 24 effective date of this Act, and that law is continued in effect for
- 25 that purpose.
- SECTION 3. This Act takes effect September 1, 2021.