

SENATE
STATE OF MINNESOTA
NINETY-THIRD SESSION

S.F. No. 1948

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| DATE | D-PG | OFFICIAL STATUS |
|------------|-------|---|
| 02/20/2023 | 920 | Introduction and first reading |
| | | Referred to Commerce and Consumer Protection |
| 03/08/2023 | 1422a | Comm report: To pass as amended and re-refer to Health and Human Services See SF2995 |

1.1 A bill for an act

1.2 relating to insurance; requiring health plans to provide coverage for biomarker

1.3 testing; amending Minnesota Statutes 2022, section 256B.0625, by adding a

1.4 subdivision; proposing coding for new law in Minnesota Statutes, chapter 62Q.

1.5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.6 Section 1. 62Q.473 **BIOMARKER TESTING.**

1.7 Subdivision 1. **Definitions.** (a) For the purposes of this section, the terms defined in this

1.8 subdivision have the meanings given.

1.9 (b) "Biomarker" means a characteristic that is objectively measured and evaluated as an

1.10 indicator of normal biological processes, pathogenic processes, or pharmacologic responses

1.11 to a specific therapeutic intervention, including but not limited to known gene-drug

1.12 interactions for medications being considered for use or already being administered.

1.13 Biomarkers include but are not limited to gene mutations, characteristics of genes, or protein

1.14 expression.

1.15 (c) "Biomarker testing" means the analysis of an individual's tissue, blood, or other

1.16 biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited

1.17 to single-analyst tests; multiplex panel tests; protein expression; and whole exome, whole

1.18 genome, and whole transcriptome sequencing.

1.19 (d) "Clinical utility" means a test provides information that is used to formulate a

1.20 treatment or monitoring strategy that informs a patient's outcome and impacts the clinical

1.21 decision. The most appropriate test may include information that is actionable and some

1.22 information that cannot be immediately used to formulate a clinical decision.

2.1 (e) "Consensus statement" means a statement that (1) describes optimal clinical care
2.2 outcomes, based on the best available evidence, for a specific clinical circumstance; and
2.3 (2) is developed by an independent, multidisciplinary panel of experts that (i) uses a rigorous
2.4 and validated development process that includes a transparent methodology and reporting
2.5 structure, and (ii) strictly adheres to the panel's conflict of interest policy.

2.6 (f) "Nationally recognized clinical practice guideline" means an evidence-based clinical
2.7 practice guideline that (1) establishes a standard of care informed by (i) a systematic review
2.8 of evidence, and (ii) an assessment of the risks and benefits of alternative care options; and
2.9 (2) is developed by an independent organization or medical professional society that (i)
2.10 uses a transparent methodology and reporting structure, and (ii) adheres to a conflict of
2.11 interest policy. Nationally recognized clinical practice guideline includes recommendations
2.12 to optimize patient care.

2.13 Subd. 2. **Biomarker testing; coverage required.** (a) A health plan must provide coverage
2.14 for biomarker testing to diagnose, treat, manage, and monitor illness or disease if the test
2.15 provides clinical utility. For purposes of this section, a test's clinical utility may be
2.16 demonstrated by medical and scientific evidence, including but not limited to:

2.17 (1) nationally recognized clinical practice guidelines as defined in this section;

2.18 (2) consensus statements as defined in this section;

2.19 (3) labeled indications for a United States Food and Drug Administration (FDA)-approved
2.20 or FDA-cleared test, indicated tests for an FDA-approved drug, or adherence to warnings
2.21 and precautions on FDA-approved drug labels; or

2.22 (4) Centers for Medicare and Medicaid Services national coverage determinations or
2.23 Medicare Administrative Contractor local coverage determinations.

2.24 (b) Coverage under this section must be provided in a manner that limits disruption of
2.25 care, including the need for multiple biopsies or biospecimen samples.

2.26 (c) Nothing in this section prohibits a health plan company from requiring a prior
2.27 authorization or imposing other utilization controls when approving coverage for biomarker
2.28 testing.

2.29 **EFFECTIVE DATE.** This section is effective January 1, 2025, and applies to health
2.30 plans offered, issued, or renewed on or after that date.

3.1 Sec. 2. Minnesota Statutes 2022, section 256B.0625, is amended by adding a subdivision
3.2 to read:

3.3 Subd. 68. **Biomarker testing.** Medical assistance covers biomarker testing to diagnose,
3.4 treat, manage, and monitor illness or disease. Medical assistance coverage must meet the
3.5 requirements that would otherwise apply to a health plan under section 62Q.473.

3.6 **EFFECTIVE DATE.** This section is effective January 1, 2025, or upon federal approval,
3.7 whichever is later.