



Sen. Julie A. Morrison

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10400SB3509sam001

LRB104 19966 BAB 35345 a

1 AMENDMENT TO SENATE BILL 3509

2 AMENDMENT NO. _____. Amend Senate Bill 3509 by replacing
3 everything after the enacting clause with the following:

4 "Section 5. The Illinois Insurance Code is amended by
5 changing Section 356z.46 as follows:

6 (215 ILCS 5/356z.46)

7 Sec. 356z.46. Biomarker testing.

8 (a) As used in this Section:

9 "Biomarker" means a characteristic that is objectively
10 measured and evaluated as an indicator of normal biological
11 processes, pathogenic processes, or pharmacologic responses to
12 a specific therapeutic intervention, including known gene-drug
13 interactions for medications being considered for use or
14 already being used. "Biomarker" includes, but is not limited
15 to, gene mutations, characteristics of genes, or protein
16 expression.

1 "Biomarker testing" means the analysis of a patient's
2 tissue, blood, or other ~~fluid~~ biospecimen for the presence of
3 a biomarker. "Biomarker testing" includes, but is not limited
4 to, single-analyte tests, multi-plex panel tests, protein
5 expression whole exome, and partial or whole genome, and whole
6 transcriptome sequencing and other genomic or molecular
7 sequencing.

8 "Consensus statement" means a statement developed by an
9 independent, multidisciplinary panel of experts using a
10 transparent methodology and reporting structure, with a
11 conflict of interest policy, that is aimed at specific
12 clinical circumstances, and the statement is based on the best
13 available evidence for the purpose of optimizing the outcomes
14 of clinical care.

15 "Nationally recognized clinical practice guidelines" means
16 evidence-based clinical practice guidelines developed by
17 independent organizations or medical professional societies
18 using a transparent methodology and reporting structure, with
19 a conflict of interest policy, that establish standards of
20 care informed by a systematic review of evidence and an
21 assessment of the benefits and risks of alternative care
22 options and that include recommendations intended to optimize
23 patient care.

24 (b) A group or individual policy of accident and health
25 insurance or managed care plan amended, delivered, issued, or
26 renewed on or after January 1, 2022 shall include coverage for

1 biomarker testing as defined in this Section pursuant to
2 criteria established under subsection (d).

3 (c) Biomarker testing shall be covered and conducted in an
4 efficient manner to provide the most complete range of results
5 to the patient's health care provider without requiring
6 multiple biopsies, biospecimen samples, or other delays or
7 disruptions in patient care.

8 (d) Biomarker testing must be covered for the purposes of
9 diagnosis, treatment, appropriate management, or ongoing
10 monitoring of an enrollee's disease or condition when the test
11 is supported by medical and scientific evidence, including,
12 but not limited to, any one of the following:

13 (1) labeled indications for an FDA-approved or
14 FDA-cleared test; ~~or~~

15 (2) indicated tests for an FDA-approved drug;

16 (3) warnings and precautions on FDA-approved drug
17 labels;

18 (4) ~~(2)~~ federal Centers for Medicare and Medicaid
19 Services National Coverage Determinations or any Medicare
20 Administrative Contractor (MAC) Local Coverage
21 Determinations and associated Local Coverage Articles; or

22 (5) testing recommendations or considerations from:

23 (A) ~~(3)~~ nationally recognized clinical practice
24 guidelines; or

25 (B) a consensus statement.

26 ~~(4) consensus statements;~~

1 ~~(5) professional society recommendations;~~

2 ~~(6) peer reviewed literature, biomedical compendia,~~
3 ~~and other medical literature that meet the criteria of the~~
4 ~~National Institutes of Health's National Library of~~
5 ~~Medicine for indexing in Index Medicus, Excerpta Medicus,~~
6 ~~Medline, and MEDLARS database of Health Services~~
7 ~~Technology Assessment Research; and~~

8 ~~(7) peer reviewed scientific studies published in or~~
9 ~~accepted for publication by medical journals that meet~~
10 ~~nationally recognized requirements for scientific~~
11 ~~manuscripts and that submit most of their published~~
12 ~~articles for review by experts who are not part of the~~
13 ~~editorial staff.~~

14 (e) The requirements set forth in this Section are subject
15 to and shall operate in accordance with Section 20 of the Prior
16 Authorization Reform Act and Section 35 of the Managed Care
17 Reform and Patient Rights Act. ~~When coverage of biomarker~~
18 ~~testing for the purpose of diagnosis, treatment, or ongoing~~
19 ~~monitoring of any medical condition is restricted for use by a~~
20 ~~group or individual policy of accident and health insurance or~~
21 ~~managed care plan, the patient and prescribing practitioner~~
22 ~~shall have access to a clear, readily accessible, and~~
23 ~~convenient processes to request an exception. The process~~
24 ~~shall be made readily accessible on the insurer's website.~~

25 (f) The changes made to this Section by this amendatory
26 Act of the 104th General Assembly apply to policies,

1 contracts, and certificates of insurance amended, delivered,
2 issued, or renewed on or after January 1, 2028.

3 (Source: P.A. 102-203, eff. 1-1-22; 102-813, eff. 5-13-22.)

4 Section 99. Effective date. This Act takes effect January
5 1, 2028.".