SB3509

LRB104 19966 BAB 33416 b

104TH GENERAL ASSEMBLY

State of Illinois

2025 and 2026

SB3509

Introduced 2/5/2026, by Sen. Julie A. Morrison

SYNOPSIS AS INTRODUCED:

215 ILCS 5/356z.46

Amends the Illinois Insurance Code. In provisions concerning biomarker testing: makes changes to defined terms; requires applicable health insurers, nonprofit health service plans, and health maintenance organizations to update and make publicly available medical policies and coverage guidelines within 90 days after the effective date of the amendatory Act; provides that, if a health insurer or nonprofit health service plan denies a claim for coverage of testing that is supported by any specified evidence, the insurer or nonprofit health service plan shall provide to the requesting entity specific written justification explaining in detail why the claim for coverage was denied as it pertains to the individual for whom the test was ordered; sets forth provisions concerning utilization review and prior authorization; provides that the Department of Insurance may conduct periodic audits and reviews to ensure entity compliance; and makes other changes.

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A BILL FOR

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

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

(215 ILCS 5/356z.46)

Sec. 356z.46. Biomarker testing.

(a) As used in this Section:

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

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

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

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

(b) A group or individual policy of accident and health insurance or managed care plan amended, delivered, issued, or renewed on or after January 1, 2022 shall include coverage for biomarker testing as defined in this Section pursuant to criteria established under subsection (d).

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

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

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

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

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

(4) ~~(2)~~ federal Centers for Medicare and Medicaid Services National Coverage Determinations or any Medicare Administrative Contractor (MAC) Local Coverage Determinations and associated Local Coverage Articles, regardless of jurisdiction; or

(5) testing recommendations or considerations from:

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

(B) a consensus statement.

~~(4) consensus statements;~~

~~(5) professional society recommendations;~~

~~(6) peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus, Medline, and MEDLARS database of Health Services~~

~~Technology Assessment Research; and~~

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

(e) When coverage of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is restricted for use by a group or individual policy of accident and health insurance or managed care plan, the patient and prescribing practitioner shall have access to a clear, readily accessible, and convenient processes to request an exception. The process shall be made readily accessible on the insurer's website.

(f) Health insurers, nonprofit health service plans, including health carriers and health benefit plans, and health maintenance organizations subject to this Section must update and make publicly available medical policies and coverage guidelines within 90 days after the effective date of this amendatory Act of the 104th General Assembly. Any updates or changes to medical policies impacting coverage of biomarker testing must be made publicly available 30 days before the effective date of the updated policy.

(g) If a health insurer or nonprofit health service plan, including a health carrier or a health benefit plan, denies a

claim for coverage of testing that is supported by any evidence in subsection (b), the insurer or nonprofit health service plan shall provide to the requesting entity, including a provider, individual, or laboratory, specific written justification explaining in detail why the claim for coverage was denied as it pertains to the individual for whom the test was ordered.

(h) If utilization review, including, but not limited to, prior authorization, is required, the health insurer, nonprofit health service plan, health maintenance organization, utilization review entity, or any third party acting on behalf of an organization or entity subject to this Section must approve or deny a prior authorization request and notify the enrollee, the enrollee's health care provider, and any entity requesting authorization of the service within 72 hours of the approval or denial for nonurgent requests or within 24 hours for urgent requests.

(i) If prior authorization is required, requests for biomarker tests may be submitted by:

(1) the ordering or treating provider;

(2) the rendering laboratory provider; or

(3) the enrollee or enrollee's representative.

(j) The Department may conduct periodic audits and reviews to ensure entity compliance with this Section.

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