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; 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) The requirements set forth in this Section are subject to and shall operate in accordance with subsection (b) of Section 20 of the Prior Authorization Reform Act and Section 45 of the Managed Care Reform and Patient Rights Act. ~~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) The changes made to this Section by this amendatory Act of the 104th General Assembly apply to policies, contracts, and certificates of insurance amended, delivered, issued, or renewed on or after January 1, 2028.

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

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