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## National Council of Insurance Legislators (NCOIL)

### Biomarker Testing Insurance Coverage Model Act

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*\*Sponsored by Asw. Pam Hunter (NY) – NCOIL Treasurer*

*\*Co-sponsored by Sen. Paul Utke (MN) – NCOIL Secretary*

*\*Draft as of June 20 2023. To be discussed and considered during the Health Insurance & Long Term Care Issues Committee Meeting on July 20, 2023.*

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#### **Section 1. Title**

This Act shall be known and cited as the “[State] Biomarker Testing Insurance Coverage Act.”

#### **Section 2. Definitions**

(a) “Biomarker” means a defined characteristic that is ~~objectively measured and evaluated~~ as an indicator of normal biological processes, pathogenic processes, or ~~pharmacologic~~ responses to an exposure or specific therapeutic intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. ~~A B~~ biomarkers is not an assessment of how a patient feels, functions, or survives ~~include but are not limited to gene mutations or protein expression.~~

(b) “Biomarker testing” ~~means~~ the analysis of a patient’s tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to single-analyte tests; and multi-plex panel tests performed at a participating in-network laboratory facility that is either CLIA certified or CLIA waived by the federal food and drug administration, and whole genome sequencing.

(c) “Clinical utility” means the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

~~(e) “Consensus statements” as used here are statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the outcomes of clinical care.~~

(d) “Nationally recognized clinical practice guidelines” as used here are evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

### **Section 3. Health Insurer Requirements**

(a) Health insurers, nonprofit health service plans, and health maintenance organizations issuing, amending, delivering or renewing a health insurance contract on or after [DATE] shall include coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person’s disease or condition to guide treatment decisions when the test provides clinical utility to the patient ~~is demonstrated~~ supported by medical and scientific evidence, including, but not limited to:

1. labeled indications for a test approved or cleared by the Food and Drug Administration (FDA) of the United States government or indicated tests for an FDA approved drug;
2. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
3. Nationally recognized clinical practice guidelines ~~and consensus statements.~~

(b) Such coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(c) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this Section. Such process shall be made readily accessible on the health insurer's, nonprofit health service plan's, or health maintenance organization's website.

(d) Nothing in this Section shall be construed to require coverage of biomarker testing for screening purposes.

#### **Section 4. Medicaid Coverage Requirements**

(a) The State Medical Assistance Program (Medicaid Program) shall cover biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a recipient's disease or condition to guide treatment decisions when the test provides clinical utility to the patient as demonstrated supported by medical and scientific evidence, including, but not limited to:

1. labeled indications for a test approved or cleared by the Food and Drug Administration (FDA) of the United States government or indicated tests for an FDA approved drug;
2. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
3. Nationally recognized clinical practice guidelines ~~and consensus statements.~~

(b) Risk-bearing entities contracted to the Medicaid Program to deliver services to recipients shall provide biomarker testing at the same scope, duration and frequency as the Medicaid program otherwise provides to enrollees.

(c) The recipient and participating provider shall have access to a clear, readily accessible, and convenient processes to request an exception to a coverage policy of the Medicaid Program or by risk-bearing entities contracted to the Medicaid Program. Such process shall be made readily accessible to all participating providers and enrollees online.

(d) Nothing in this Section shall be construed to require coverage of biomarker testing for screening purposes.

#### **Section 5. Rules**

The Commissioner shall adopt rules as necessary to effectuate the provisions of this Act.

**Section 6. Effective Date**

This Act shall take effect [xxxxx] and shall apply to all policies and contracts issued, renewed, modified, altered or amended on or after such date.