Article - Insurance

§15–859.

(a) (1) In this section the following words have the meanings indicated.

(2) (i) "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 administered.

(ii) "Biomarker" includes gene mutations, characteristics of genes, or protein expression.

(3) (i) "Biomarker testing" is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker, the results of which:

1. provide information that may be used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision; and

2. include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision.

(ii) "Biomarker testing" includes single–analyte tests, multi–plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(b) This section applies to:

(1) insurers and nonprofit health service plans that provide hospital, medical, or surgical benefits to individuals or groups on an expense–incurred basis under health insurance policies or contracts that are issued or delivered in the State; and

(2) health maintenance organizations that provide hospital, medical, or surgical benefits to individuals or groups under contracts that are issued or delivered in the State.

(c) An entity subject to this section shall provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition that is supported by medical and scientific evidence, including testing:

(1) cleared or approved by the U.S. Food and Drug Administration;

(2) required or recommended for a drug approved by the U.S. Food and Drug Administration to ensure an insured or enrollee is a good candidate for the drug treatment;

(3) required or recommended through a warning or precaution for a drug approved by the U.S. Food and Drug Administration to identify whether an insured or enrollee will have an adverse reaction to the drug treatment or dosage;

(4) covered under a Centers for Medicare and Medicaid Services National Coverage Determination or Medicare Administrative Contractor Local Coverage Determination; or

(5) supported by nationally recognized clinical practice guidelines that are:

(i) developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and that have a conflict of interest policy; and

(ii) established standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

(d) An entity subject to this section shall ensure that the coverage required under subsection (c) of this section is provided in a manner that limits disruptions in care including the need for multiple biopsies or biospecimen samples.

(e) (1) Subject to paragraph (2) of this subsection, the coverage required under this section may be subject to the annual deductibles, copayments, or coinsurance requirements imposed by an entity subject to this section for similar coverages under the same health insurance policy or contract.

(2) The annual deductibles, copayments, or coinsurance requirements imposed under paragraph (1) of this subsection for the coverage required under this section may not be greater than the annual deductibles, copayments, or coinsurance requirements imposed by the entity for similar coverages.