Proposed Substitute Bill No. 307

LCO No. **3295**

AN ACT CONCERNING MEDICAID COVERAGE OF BIOMARKER TESTING.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2024*) (a) As used in this section:

(1) "Biomarker" means a characteristic, including, but not limited to, a gene mutation or protein expression that can be objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention for a disease or condition.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker, including, but not limited to, tests for a single substance, tests for multiple substances, diseases or conditions, and whole genome sequencing.

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict-of-interest policy that are (A) aimed at specific clinical circumstances, and (B) based on the best available evidence for the purpose of optimizing clinical care outcomes.

(4) "Nationally recognized clinical practice guidelines" means evidence-based guidelines developed by independent organizations or medical professional societies utilizing transparent methodologies and reporting structures and conflict-of-interest policies that (A) establish

standards of care informed by a systematic review of evidence and assessments of the benefits and costs of alternative care options, and (B) include recommendations intended to optimize patient care.

(b) The Commissioner of Social Services, to the extent permissible under federal law, shall provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management or ongoing monitoring of a Medicaid enrollee's disease or condition. The commissioner shall condition such coverage on medical and scientific evidence supporting such test, including, but not limited to, (1) approval of such test by the federal Food and Drug Administration or recommendations on labels of drugs approved by the federal Food and Drug Administration to conduct such test, (2) national coverage determinations or local coverage determinations for Medicare Administrative Contractors by the Centers for Medicare and Medicaid Services, (3) nationally recognized clinical practice guidelines and consensus statements, or (4) any other sources for establishing medical necessity in accordance with section 17b-259b of the general statutes.

(c) Nothing in this section shall be construed to limit the ability of the Department of Social Services to require prior authorization to ensure that a request for testing meets the standards under this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2024*	New section