GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2025

HOUSE BILL 567
Committee Substitute Favorable 4/29/25

Short Title: Ensure Access to Biomarker Testing. (Public)

Sponsors:

Referred to:

March 31, 2025

A BILL TO BE ENTITLED

AN ACT TO ENSURE ACCESS TO AN EARLY AND ACCURATE DIAGNOSIS OF DEMENTIA IN ORDER TO IMPROVE ACCESS TO CARE AND SUPPORT SERVICES FOR, ENHANCE THE QUALITY OF LIFE OF, AND REDUCE THE FINANCIAL IMPACT OF THE CONDITION ON NORTH CAROLINIANS.

The General Assembly of North Carolina enacts:

PART I. HEALTH BENEFIT PLAN COVERAGE OF BIOMARKER TESTING

SECTION 1.1.(a) Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-216. Coverage of biomarker testing.**

(a) The following definitions apply in this section:

(1) Biomarker. – 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 medication being considered for use or already being administered. This term incudes gene mutations, characteristics of genes, and protein expression.

(2) Biomarker testing. – The analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. This term includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(3) Consensus statement. – A statement that is developed by an independent multidisciplinary panel, aimed at specific clinical circumstances, and based upon the best available evidence for the purpose of optimizing the outcomes of clinical care.

(4) FDA. – The United States Food and Drug Administration.

(5) Reserved for future codification purposes.

(6) Independent multidisciplinary panel. – A multidisciplinary panel of experts that utilizes a transparent methodology and reporting structure and that has a conflict of interest policy.

(7) Independent organization or medical professional society. – An organization or medical professional society that utilizes a transparent methodology and reporting structure and that has a conflict of interest policy.

(8) Reserved for future codification purposes.

(9) Nationally recognized clinical practice guidelines. – Evidence-based clinical practice guidelines developed by independent organizations or medical professional societies that establish standards of care that are 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 health benefit plan shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate care management, or ongoing monitoring of an insured's disease or condition when the testing is supported by medical and scientific evidence. At a minimum, any of the following shall be considered support for biomarker testing:

(1) Label indications for a test that has been FDA-approved or FDA-cleared.

(2) Indicated tests for an FDA-approved drug.

(3) Warnings and precautions on an FDA-approved drug label.

(4) National coverage determinations developed by the Centers for Medicare and Medicaid Services.

(5) Local coverage determinations developed by a Medicare Administrative Contractor.

(6) Nationally recognized clinical practice guidelines and consensus statements.

(c) Coverage required under this section shall be provided in a manner that limits disruption in patient care, including the need for multiple biopsies or biospecimen samples."

SECTION 1.1.(b) G.S. 58-3-215, as amended by subsection (c) of this section, reads as rewritten:

"**§ 58-3-215. Genetic and biomarker information in health insurance.**

(a) Definitions. – ~~As used~~ The following definitions apply in this section:

(1) Biomarker. – 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 medication being considered for use or already being administered. This term incudes gene mutations, characteristics of genes, and protein expression.

(1a) ~~"Genetic information" means information~~ Genetic information. – Information about genes, gene products, or inherited characteristics that may derive from an individual or a family member. "Genetic information" does not include the results of routine physical measurements, blood chemistries, blood counts, urine analyses, tests for abuse of drugs, and tests for the presence of human immunodeficiency virus.

…

(c) No insurer ~~shall:~~shall do any of the following:

(1) Raise the premium or contribution rates paid by a group for a group health benefit plan on the basis of genetic or biomarker information obtained about an individual member of the group.

(2) Refuse to issue or deliver a health benefit plan because of genetic or biomarker information obtained about any person to be insured by the health benefit plan.

(3) Charge a higher premium rate or charge for a health benefit plan because of genetic or biomarker information obtained about any person to be insured by the health benefit plan.

…."

SECTION 1.1.(c) G.S. 58-3-215(a)(2) and G.S. 58-3-215(a)(3) are repealed.

SECTION 1.1.(d) This section is effective October 1, 2025, and applies to insurance contracts issued, renewed, or amended on or after that date.

SECTION 1.2.(a) G.S. 135-48.51 reads as rewritten:

"**§ 135-48.51. Coverage and operational mandates related to Chapter 58 of the General Statutes.**

The following provisions of Chapter 58 of the General Statutes apply to the State Health Plan:

(1) G.S. 58-3-191, Managed care reporting and disclosure requirements.

(1a) G.S. 58-3-216, Coverage of biomarker testing.

…."

SECTION 1.2.(b) This section becomes effective October 1, 2025, and applies as of the start of the next plan year following the effective date.

PART II. MEDICAID COVERAGE OF BIOMARKER TESTING

SECTION 2.1. The Department of Health and Human Services, Division of Health Benefits (DHB), shall ensure coverage for biomarker testing under the laboratory services clinical coverage policies 1S-1 through 1S-13 to the same extent those services are required to be covered by a health benefit plan under G.S. 58-3-216.

PART III. EFFECTIVE DATE

SECTION 3.1. Except as otherwise provided, this act is effective when it becomes law.