The House Committee on Insurance offers the following substitute to HB 85:

A BILL TO BE ENTITLED
AN ACT

To amend Article 1 of Chapter 24 of Title 33 of the Official Code of Georgia Annotated, relating to general provisions regarding insurance, so as to require health benefit policy coverage for biomarker testing if supported by medical and scientific evidence; to provide for definitions; to provide for requirements; to provide conditions relating to prior authorization; to provide for processes to request exceptions or appeal adverse determinations; to amend Article 7 of Chapter 4 of Title 49 of the Official Code of Georgia Annotated, relating to medical assistance generally, so as to provide for coverage for biomarker testing if supported by medical and scientific evidence; to provide for definitions; to provide for requirements; to provide conditions relating to prior authorization; to provide for processes to request exceptions or appeal adverse determinations; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Article 1 of Chapter 24 of Title 33 of the Official Code of Georgia Annotated, relating to general provisions regarding insurance, is amended by adding a new Code section to read as follows:

"33-24-59.33.

(a) As used in this Code section, the term:

(1) '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. Such term includes, but is not limited to, gene mutations, protein expression, known gene-drug interactions for medications, and characteristics of genes.

(2) 'Biomarker testing' means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Such term includes, but is not limited to, single-analyte tests, multiplex panel tests, whole genome sequencing, protein expression, whole exome, and whole transcriptome.

(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. Such 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.

(4) 'Health benefit policy' means any individual or group plan, policy, or contract for healthcare services issued, delivered, issued for delivery, or renewed in this state which provides major medical benefits, including those contracts executed by the State of Georgia on behalf of state employees under Article 1 of Chapter 18 of Title 45, by a health care corporation, health maintenance organization, preferred provider organization, accident and sickness insurer, fraternal benefit society, hospital service corporation, medical service corporation, or other insurer or similar entity.

(5) 'Nationally recognized clinical practice guidelines' means 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. Such guidelines establish 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.

(b) All health benefit policies renewed or issued on or after July 1, 2023, shall include coverage for biomarker testing as provided in this Code section.

(c) Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the testing is supported by medical and scientific evidence, including, but not limited to:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA);

(2) An indicated test for an FDA approved drug;

(3) A national coverage determination made by the federal Centers for Medicare and Medicaid Services or a local coverage determination made by a medicare administrative contractor;

(4) Nationally recognized clinical practice guidelines and consensus statements; or

(5) Warnings and precautions on FDA approved drugs.

(d) Health benefit policies shall ensure biomarker testing coverage is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(e) The insurer or similar entity subject to this Code section shall approve or deny a prior authorization request and notify the enrollee and the enrollee's healthcare provider within seven calendar days for nonurgent requests or within 72 hours for urgent requests. If the insurer or similar entity fails to respond in accordance with such time frames, such request shall be deemed approved.

(f) Enrollees, healthcare providers, and testing service providers shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy or an adverse utilization review determination under a health benefit policy, including, but not limited to, the rights of consumers under Article 2 of Chapter 20A of

Title 33, the 'Patient's Right to Independent Review Act.' Such process shall be made readily accessible on the insurer's or similar entity's website."

SECTION 2.

Article 7 of Chapter 4 of Title 49 of the Official Code of Georgia Annotated, relating to medical assistance generally, is amended by adding a new Code section to read as follows:

"49-4-159.2.

(a) As used in this Code section, the term:

(1) '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. Such term includes, but is not limited to, gene mutations, protein expression, known gene-drug interactions for medications, and characteristics of genes.

(2) 'Biomarker testing' means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Such term includes, but is not limited to, single-analyte tests, multiplex panel tests, whole genome sequencing, protein expression, whole exome, and whole transcriptome.

(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. Such 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.

(4) 'Nationally recognized clinical practice guidelines' means 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. Such guidelines establish 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.

(b) The department shall provide biomarker testing for Medicaid recipients in accordance with the requirements of this Code section.

(c) Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the testing is supported by medical and scientific evidence, including, but not limited to:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA);

(2) An indicated test for an FDA approved drug;

(3) A national coverage determination made by the federal Centers for Medicare and Medicaid Services or a local coverage determination made by a medicare administrative contractor;

(4) Nationally recognized clinical practice guidelines and consensus statements; or

(5) Warnings and precautions on FDA approved drugs.

(d) Care management organizations shall provide biomarker testing as required by this Code section at the same scope, duration, and frequency as the Medicaid program otherwise provides to recipients of medical assistance.

(e) A care management organization or its agent shall approve or deny a prior authorization request and notify the recipient and the provider of medical assistance within seven calendar days for nonurgent requests or within 72 hours for urgent requests. If the care management organization or its agent fails to respond in accordance with such time frames, such request shall be deemed approved.

(f) Recipients of medical assistance, providers of medical assistance, and testing service providers shall be afforded the fair hearing rights provided pursuant to Code Section 49-4-153 or the state plan provided for in Article 13 of Chapter 5 of Title 49 to request an exception to a coverage policy or an adverse utilization review determination by a care

management organization or its agent. Such hearing rights shall be made readily accessible on the department's and care management organization's websites."

SECTION 3.

All laws and parts of laws in conflict with this Act are repealed.