SENATE BILL 805

J5, J4, J1 (3lr2437)

ENROLLED BILL

— Finance/Health and Government Operations —

Introduced by **Senator Ellis**

Read and Examined by Proofreaders:

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Proofreader.

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Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____M.

_____

President.

CHAPTER _____

AN ACT concerning

Maryland Medical Assistance Program and Health Insurance – Required Coverage for Biomarker Testing

FOR the purpose of requiring the Maryland Medical Assistance Program and certain insurers, nonprofit health service plans, health maintenance organizations, and managed care organizations to provide coverage for biomarker testing that is supported by medical and scientific evidence; establishing requirements for deductibles, copayments, coinsurance, and utilization review for biomarker testing; and generally relating to the coverage of biomarker testing by the Maryland Medical Assistance Program and health insurance carriers.

BY adding to

Article – Health – General

Section 15–102.3(k) and 15–103(a)(2)(xxii)

Annotated Code of Maryland

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**

[Brackets**]** indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Italics indicate opposite chamber/conference committee amendments.

(2019 Replacement Volume and 2022 Supplement)

BY repealing and reenacting, without amendments,
Article – Health – General
Section 15–103(a)(1)
Annotated Code of Maryland
(2019 Replacement Volume and 2022 Supplement)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 15–103(a)(2)(xx) and (xxi)
Annotated Code of Maryland
(2019 Replacement Volume and 2022 Supplement)

BY adding to
Article – Insurance
Section 15–859
Annotated Code of Maryland
(2017 Replacement Volume and 2022 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

15–102.3.

(K) ~~THE~~ BEGINNING JULY 1, 2025, THE PROVISIONS OF § 15–859 OF THE INSURANCE ARTICLE APPLY TO MANAGED CARE ORGANIZATIONS IN THE SAME MANNER THEY APPLY TO CARRIERS.

15–103.

(a) (1) The Secretary shall administer the Maryland Medical Assistance Program.

(2) The Program:

(xx) Beginning on July 1, 2023, shall provide, subject to federal approval and limitations of the State budget, community violence prevention services in accordance with § 15–141.3 of this subtitle; **[**and**]**

(xxi) Beginning on January 1, 2023, shall provide, subject to the limitations of the State budget, and as permitted by federal law, coverage for self–measured blood pressure monitoring for all Program recipients diagnosed with uncontrolled high blood pressure, including:

1. The provision of validated home blood pressure monitors; and

2. Reimbursement of health care provider and other staff time used for patient training, transmission of blood pressure data, interpretation of blood pressure readings and reporting, and the delivery of co–interventions, including educational materials or classes, behavioral change management, and medication management**; AND**

(XXII) BEGINNING ON ~~JANUARY 1, 2024~~ JULY 1, 2025, SHALL PROVIDE, SUBJECT TO THE LIMITATIONS OF THE STATE BUDGET, AND AS PERMITTED BY FEDERAL LAW, COVERAGE FOR BIOMARKER TESTING IN ACCORDANCE WITH § 15–859 OF THE INSURANCE ARTICLE.

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~~; OR~~

~~(6) SUPPORTED BY CONSENSUS STATEMENTS THAT ARE:~~

~~(I) DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND THAT HAVE A CONFLICT OF INTEREST POLICY; AND~~

~~(II) 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) 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.

~~(F) (1) AN ENTITY SUBJECT TO THIS SECTION THAT REQUIRES PRIOR AUTHORIZATION OR A SIMILAR UTILIZATION REVIEW PROCEDURE FOR THE COVERAGE REQUIRED UNDER SUBSECTION (C) OF THIS SECTION SHALL MAKE A DETERMINATION REGARDING A REQUEST FOR APPROVAL WHEN SUBMITTED ELECTRONICALLY:~~

~~(I) IN REAL TIME IF THE BIOMARKER TESTING IS TO GUIDE THE PROVISION OF PHARMACEUTICAL SERVICES THAT ARE URGENT AND NO ADDITIONAL INFORMATION IS NEEDED TO PROCESS THE REQUEST; AND~~

~~(II) FOR OTHER REQUESTS, IN ACCORDANCE WITH § 19–108.2 OF THE HEALTH – GENERAL ARTICLE.~~

~~(2) IF A RESPONSE TO A PRIOR AUTHORIZATION OR SIMILAR UTILIZATION REVIEW REQUEST FOR APPROVAL IS NOT RECEIVED IN THE TIME FRAMES REQUIRED UNDER THIS SUBSECTION, THE REQUEST SHALL BE CONSIDERED APPROVED.~~

SECTION 2. AND BE IT FURTHER ENACTED, That on or before December 1, 2024, the Maryland Department of Health shall report to the Governor and, in accordance with § 2–1257 of the State Government Article, the General Assembly on the following:

(1) the fiscal impact of the ~~biomarkers~~ *biomarker* testing coverage required under Section 1 of this Act on the Maryland Medical Assistance Program's policy on ~~biomarkers~~ *biomarker* testing coverage for specific cancers during fiscal year 2024;

(2) any available data on use of ~~biomarkers~~ *biomarker* testing by race and ethnicity in the Program;

(3) the anticipated fiscal and access impacts of expanding the coverage required under Section 1 of this Act to the Maryland Medical Assistance Program in fiscal year 2026; ~~and~~

(4) whether to establish a cap on the amount of reimbursement for ~~biomarkers~~ *biomarker* testing coverage and, if recommended:

(i) the recommended cap amount; and

(ii) the anticipated fiscal and access impacts of establishing the cap; and

~~(4)~~ (5) recommendations on any legislative changes to the requirements established under Section 1 of this Act relating to the Maryland Medical Assistance Program, including managed care organizations.

SECTION 3. AND BE IT FURTHER ENACTED, That on or before December 1, 2025, the Maryland Health Care Commission shall report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, on the impact of providing biomarker testing coverage required under Section 1 of this Act, including an analysis of the impact of providing access to biomarker testing to individuals based on race, gender, age, and public or private insurance.

SECTION ~~2.~~ 4. AND BE IT FURTHER ENACTED, That Section 1 of this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2024.

SECTION ~~3.~~ 5. AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 2024.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.