

HOUSE BILL 1217

J5, J4, J1

(3lr1505)

ENROLLED BILL

— Health and Government Operations/Finance —

Introduced by ~~Delegates Kelly, Toles, Alston, Sample-Hughes, White, and Wilkins~~
Wilkins, Bagnall, Bhandari, Chisholm, Cullison, Guzzone, Hill, Hutchinson,
S. Johnson, Kaiser, Kerr, Kipke, R. Lewis, Lopez, Martinez, M. Morgan,
Pena-Melnyk, Reilly, Rosenberg, Szeliga, Taveras, and Woods

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

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

Speaker.

CHAPTER _____

1 AN ACT concerning

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

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

11 BY adding to

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.



1 Article – Health – General
2 Section 15–102.3(k) and 15–103(a)(2)(xxii)
3 Annotated Code of Maryland
4 (2019 Replacement Volume and 2022 Supplement)

5 BY repealing and reenacting, without amendments,
6 Article – Health – General
7 Section 15–103(a)(1)
8 Annotated Code of Maryland
9 (2019 Replacement Volume and 2022 Supplement)

10 BY repealing and reenacting, with amendments,
11 Article – Health – General
12 Section 15–103(a)(2)(xx) and (xxi)
13 Annotated Code of Maryland
14 (2019 Replacement Volume and 2022 Supplement)

15 BY adding to
16 Article – Insurance
17 Section 15–859
18 Annotated Code of Maryland
19 (2017 Replacement Volume and 2022 Supplement)

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

22 **Article – Health – General**

23 15–102.3.

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

27 15–103.

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

30 (2) The Program:

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

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

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

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

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

16 **Article – Insurance**

17 **15-859.**

18 **(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS**
19 **INDICATED.**

20 **(2) (I) “BIOMARKER” MEANS A CHARACTERISTIC THAT IS**
21 **OBJECTIVELY MEASURED AND EVALUATED AS AN INDICATOR OF NORMAL**
22 **BIOLOGICAL PROCESSES, PATHOGENIC PROCESSES, OR PHARMACOLOGIC**
23 **RESPONSES TO A SPECIFIC THERAPEUTIC INTERVENTION, INCLUDING KNOWN**
24 **GENE-DRUG INTERACTIONS FOR MEDICATIONS BEING CONSIDERED FOR USE OR**
25 **ALREADY BEING ADMINISTERED.**

26 **(II) “BIOMARKER” INCLUDES GENE MUTATIONS,**
27 **CHARACTERISTICS OF GENES, OR PROTEIN EXPRESSION.**

28 **(3) (I) “BIOMARKER TESTING” IS THE ANALYSIS OF A PATIENT’S**
29 **TISSUE, BLOOD, OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER,**
30 **THE RESULTS OF WHICH:**

31 **1. PROVIDE INFORMATION THAT MAY BE USED IN THE**
32 **FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT INFORMS A**
33 **PATIENT’S OUTCOME AND IMPACTS THE CLINICAL DECISION; AND**

1 **2. INCLUDE BOTH INFORMATION THAT IS ACTIONABLE**
2 **AND SOME INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE**
3 **FORMULATION OF A CLINICAL DECISION.**

4 **(II) “BIOMARKER TESTING” INCLUDES SINGLE–ANALYTE**
5 **TESTS, MULTI–PLEX PANEL TESTS, PROTEIN EXPRESSION, AND WHOLE EXOME,**
6 **WHOLE GENOME, AND WHOLE TRANSCRIPTOME SEQUENCING.**

7 **(B) THIS SECTION APPLIES TO:**

8 **(1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT**
9 **PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS**
10 **ON AN EXPENSE–INCURRED BASIS UNDER HEALTH INSURANCE POLICIES OR**
11 **CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND**

12 **(2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE**
13 **HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS UNDER**
14 **CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.**

15 **(C) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE FOR**
16 **BIOMARKER TESTING FOR THE PURPOSE OF DIAGNOSIS, TREATMENT, APPROPRIATE**
17 **MANAGEMENT, OR ONGOING MONITORING OF A DISEASE OR CONDITION THAT IS**
18 **SUPPORTED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING TESTING:**

19 **(1) CLEARED OR APPROVED BY THE U.S. FOOD AND DRUG**
20 **ADMINISTRATION;**

21 **(2) REQUIRED OR RECOMMENDED FOR A DRUG APPROVED BY THE**
22 **U.S. FOOD AND DRUG ADMINISTRATION TO ENSURE AN INSURED OR ENROLLEE IS**
23 **A GOOD CANDIDATE FOR THE DRUG TREATMENT;**

24 **(3) REQUIRED OR RECOMMENDED THROUGH A WARNING OR**
25 **PRECAUTION FOR A DRUG APPROVED BY THE U.S. FOOD AND DRUG**
26 **ADMINISTRATION TO IDENTIFY WHETHER AN INSURED OR ENROLLEE WILL HAVE AN**
27 **ADVERSE REACTION TO THE DRUG TREATMENT OR DOSAGE;**

28 **(4) COVERED UNDER A CENTERS FOR MEDICARE AND MEDICAID**
29 **SERVICES NATIONAL COVERAGE DETERMINATION OR MEDICARE**
30 **ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE DETERMINATION; OR**

31 **(5) SUPPORTED BY NATIONALLY RECOGNIZED CLINICAL PRACTICE**
32 **GUIDELINES THAT ARE:**

1 (I) DEVELOPED BY INDEPENDENT ORGANIZATIONS OR
2 MEDICAL PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND
3 REPORTING STRUCTURE AND THAT HAVE A CONFLICT OF INTEREST POLICY; AND

4 (II) ESTABLISHED STANDARDS OF CARE INFORMED BY A
5 SYSTEMATIC REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND
6 RISKS OF ALTERNATIVE CARE OPTIONS AND INCLUDE RECOMMENDATIONS
7 INTENDED TO OPTIMIZE PATIENT CARE; ~~OR~~

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

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

12 ~~(II) AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES AND BASE~~
13 ~~THE STATEMENTS ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF~~
14 ~~OPTIMIZING THE OUTCOMES OF CLINICAL CARE.~~

15 (D) AN ENTITY SUBJECT TO THIS SECTION SHALL ENSURE THAT THE
16 COVERAGE REQUIRED UNDER SUBSECTION (C) OF THIS SECTION IS PROVIDED IN A
17 MANNER THAT LIMITS DISRUPTIONS IN CARE INCLUDING THE NEED FOR MULTIPLE
18 BIOPSIES OR BIOSPECIMEN SAMPLES.

19 (E) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, THE
20 COVERAGE REQUIRED UNDER THIS SECTION MAY BE SUBJECT TO THE ANNUAL
21 DEDUCTIBLES, COPAYMENTS, OR COINSURANCE REQUIREMENTS IMPOSED BY AN
22 ENTITY SUBJECT TO THIS SECTION FOR SIMILAR COVERAGES UNDER THE SAME
23 HEALTH INSURANCE POLICY OR CONTRACT.

24 (2) THE ANNUAL DEDUCTIBLES, COPAYMENTS, OR COINSURANCE
25 REQUIREMENTS IMPOSED UNDER PARAGRAPH (1) OF THIS SUBSECTION FOR THE
26 COVERAGE REQUIRED UNDER THIS SECTION MAY NOT BE GREATER THAN THE
27 ANNUAL DEDUCTIBLES, COPAYMENTS, OR COINSURANCE REQUIREMENTS IMPOSED
28 BY THE ENTITY FOR SIMILAR COVERAGES.

29 ~~(F) (1) AN ENTITY SUBJECT TO THIS SECTION THAT REQUIRES PRIOR~~
30 ~~AUTHORIZATION OR A SIMILAR UTILIZATION REVIEW PROCEDURE FOR THE~~
31 ~~COVERAGE REQUIRED UNDER SUBSECTION (C) OF THIS SECTION SHALL MAKE A~~
32 ~~DETERMINATION REGARDING A REQUEST FOR APPROVAL WHEN SUBMITTED~~
33 ~~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~~

~~(H) 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 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.

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

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.