

SENATE BILL 805

J5, J4, J1

3lr2437
CF 3lr1505

By: **Senator Ellis**

Introduced and read first time: February 6, 2023

Assigned to: Finance

A BILL ENTITLED

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

16 BY repealing and reenacting, without amendments,
17 Article – Health – General
18 Section 15–103(a)(1)
19 Annotated Code of Maryland
20 (2019 Replacement Volume and 2022 Supplement)

21 BY repealing and reenacting, with amendments,
22 Article – Health – General
23 Section 15–103(a)(2)(xx) and (xxi)
24 Annotated Code of Maryland
25 (2019 Replacement Volume and 2022 Supplement)

26 BY adding to
27 Article – Insurance

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Section 15–859
2 Annotated Code of Maryland
3 (2017 Replacement Volume and 2022 Supplement)

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

6 **Article – Health – General**

7 15–102.3.

8 **(K) THE PROVISIONS OF § 15–859 OF THE INSURANCE ARTICLE APPLY TO**
9 **MANAGED CARE ORGANIZATIONS IN THE SAME MANNER THEY APPLY TO CARRIERS.**

10 15–103.

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

13 (2) The Program:

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

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

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

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

28 **(XXII) BEGINNING ON JANUARY 1, 2024, SHALL PROVIDE,**
29 **SUBJECT TO THE LIMITATIONS OF THE STATE BUDGET, AND AS PERMITTED BY**
30 **FEDERAL LAW, COVERAGE FOR BIOMARKER TESTING IN ACCORDANCE WITH §**
31 **15–859 OF THE INSURANCE ARTICLE.**

32 **Article – Insurance**

1 15-859.

2 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
3 INDICATED.

4 (2) (I) "BIOMARKER" MEANS A CHARACTERISTIC THAT IS
5 OBJECTIVELY MEASURED AND EVALUATED AS AN INDICATOR OF NORMAL
6 BIOLOGICAL PROCESSES, PATHOGENIC PROCESSES, OR PHARMACOLOGIC
7 RESPONSES TO A SPECIFIC THERAPEUTIC INTERVENTION, INCLUDING KNOWN
8 GENE-DRUG INTERACTIONS FOR MEDICATIONS BEING CONSIDERED FOR USE OR
9 ALREADY BEING ADMINISTERED.

10 (II) "BIOMARKER" INCLUDES GENE MUTATIONS,
11 CHARACTERISTICS OF GENES, OR PROTEIN EXPRESSION.

12 (3) (I) "BIOMARKER TESTING" IS THE ANALYSIS OF A PATIENT'S
13 TISSUE, BLOOD, OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

14 (II) "BIOMARKER TESTING" INCLUDES SINGLE-ANALYTE
15 TESTS, MULTI-PLEX PANEL TESTS, PROTEIN EXPRESSION, AND WHOLE EXOME,
16 WHOLE GENOME, AND WHOLE TRANSCRIPTOME SEQUENCING.

17 (B) THIS SECTION APPLIES TO:

18 (1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT
19 PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS
20 ON AN EXPENSE-INCURRED BASIS UNDER HEALTH INSURANCE POLICIES OR
21 CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND

22 (2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE
23 HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS UNDER
24 CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

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

29 (1) CLEARED OR APPROVED BY THE U.S. FOOD AND DRUG
30 ADMINISTRATION;

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

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

8 **(4) COVERED UNDER A CENTERS FOR MEDICARE AND MEDICAID**
9 **SERVICES NATIONAL COVERAGE DETERMINATION OR MEDICARE**
10 **ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE DETERMINATION;**

11 **(5) SUPPORTED BY NATIONALLY RECOGNIZED CLINICAL PRACTICE**
12 **GUIDELINES THAT ARE:**

13 **(I) DEVELOPED BY INDEPENDENT ORGANIZATIONS OR**
14 **MEDICAL PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND**
15 **REPORTING STRUCTURE AND THAT HAVE A CONFLICT OF INTEREST POLICY; AND**

16 **(II) ESTABLISHED STANDARDS OF CARE INFORMED BY A**
17 **SYSTEMATIC REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND**
18 **RISKS OF ALTERNATIVE CARE OPTIONS AND INCLUDE RECOMMENDATIONS**
19 **INTENDED TO OPTIMIZE PATIENT CARE; OR**

20 **(6) SUPPORTED BY CONSENSUS STATEMENTS THAT ARE:**

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

24 **(II) AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES AND BASE**
25 **THE STATEMENTS ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF**
26 **OPTIMIZING THE OUTCOMES OF CLINICAL CARE.**

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

31 **(E) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, THE**
32 **COVERAGE REQUIRED UNDER THIS SECTION MAY BE SUBJECT TO THE ANNUAL**
33 **DEDUCTIBLES, COPAYMENTS, OR COINSURANCE REQUIREMENTS IMPOSED BY AN**

1 ENTITY SUBJECT TO THIS SECTION FOR SIMILAR COVERAGES UNDER THE SAME
2 HEALTH INSURANCE POLICY OR CONTRACT.

3 (2) THE ANNUAL DEDUCTIBLES, COPAYMENTS, OR COINSURANCE
4 REQUIREMENTS IMPOSED UNDER PARAGRAPH (1) OF THIS SUBSECTION FOR THE
5 COVERAGE REQUIRED UNDER THIS SECTION MAY NOT BE GREATER THAN THE
6 ANNUAL DEDUCTIBLES, COPAYMENTS, OR COINSURANCE REQUIREMENTS IMPOSED
7 BY THE ENTITY FOR SIMILAR COVERAGES.

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

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

16 (II) FOR OTHER REQUESTS, IN ACCORDANCE WITH §
17 19-108.2 OF THE HEALTH – GENERAL ARTICLE.

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

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

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