

# SENATE BILL 961

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By: **Senator Mautz**

Introduced and read first time: January 28, 2025

Assigned to: Finance

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## A BILL ENTITLED

1 AN ACT concerning

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

4 FOR the purpose of requiring the Maryland Medical Assistance Program and certain health  
5 insurers, nonprofit health services plans, and health maintenance organizations to  
6 provide coverage for single-gene and multigene pharmacogenomic testing in certain  
7 circumstances; limiting the prior authorization requirements that certain health  
8 insurers, nonprofit health services plans, and health maintenance organizations may  
9 implement for pharmacogenomic testing; and generally relating to coverage of  
10 pharmacogenomic testing.

11 BY adding to  
12 Article – Health – General  
13 Section 15–102.3(m) and 15–103(a)(2)(xxv)  
14 Annotated Code of Maryland  
15 (2023 Replacement Volume and 2024 Supplement)

16 BY repealing and reenacting, without amendments,  
17 Article – Health – General  
18 Section 15–103(a)(1)  
19 Annotated Code of Maryland  
20 (2023 Replacement Volume and 2024 Supplement)

21 BY repealing and reenacting, with amendments,  
22 Article – Health – General  
23 Section 15–103(a)(2)(xxiii) and (xxiv)  
24 Annotated Code of Maryland  
25 (2023 Replacement Volume and 2024 Supplement)

26 BY adding to  
27 Article – Insurance

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Section 15–861  
2 Annotated Code of Maryland  
3 (2017 Replacement Volume and 2024 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 **(M) (1) BEGINNING JULY 1, 2026, THE PROVISIONS OF § 15–861(C) AND**  
9 **(D) OF THE INSURANCE ARTICLE APPLY TO MANAGED CARE ORGANIZATIONS IN THE**  
10 **SAME MANNER THEY APPLY TO CARRIERS.**

11 **(2) A MANAGED CARE ORGANIZATION THAT DOES NOT COMPLY WITH**  
12 **§ 15–861(C) AND (D) OF THE INSURANCE ARTICLE SHALL BE SUBJECT TO A**  
13 **MONETARY PENALTY OF UP TO \$10,000 PER INSTANCE OF NONCOMPLIANCE AND AN**  
14 **ADDITIONAL PENALTY OF \$1,000 PER DAY FOR EACH DAY THE NONCOMPLIANCE**  
15 **CONTINUES AFTER NOTIFICATION OF NONCOMPLIANCE FROM THE DEPARTMENT**  
16 **TO THE MANAGED CARE ORGANIZATION.**

17 **(3) (I) THE DEPARTMENT MAY REQUIRE A MANAGED CARE**  
18 **ORGANIZATION THAT DOES NOT COMPLY WITH § 15–861(C) AND (D) OF THE**  
19 **INSURANCE ARTICLE TO SUBMIT AND IMPLEMENT A CORRECTIVE ACTION PLAN**  
20 **WITHIN 30 DAYS AFTER RECEIPT OF A REQUEST FOR A CORRECTIVE ACTION PLAN**  
21 **FROM THE DEPARTMENT.**

22 **(II) FAILURE TO IMPLEMENT A CORRECTIVE ACTION PLAN**  
23 **REQUIRED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH MAY RESULT IN**  
24 **ADDITIONAL ENFORCEMENT ACTIONS.**

25 **(4) A MANAGED CARE ORGANIZATION SUBJECT TO A PENALTY UNDER**  
26 **THIS SUBSECTION MAY REQUEST AN ADMINISTRATIVE HEARING UNDER TITLE 10,**  
27 **SUBTITLE 2 OF THE STATE GOVERNMENT ARTICLE.**

28 **(5) (I) THE DEPARTMENT SHALL CONDUCT PERIODIC AUDITS AND**  
29 **REVIEWS OF MANAGED CARE ORGANIZATIONS TO DETERMINE COMPLIANCE WITH**  
30 **THIS SUBSECTION.**

31 **(II) THE DEPARTMENT SHALL ESTABLISH A PROCESS FOR**  
32 **PATIENTS, PRESCRIBERS, AND LABORATORIES TO REPORT INSTANCES OF**  
33 **NONCOMPLIANCE WITH THIS SUBSECTION.**

1 15-103.

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

4 (2) The Program:

5 (xxiii) Beginning on July 1, 2025, shall provide, subject to the  
6 limitations of the State budget, and as permitted by federal law, coverage for biomarker  
7 testing in accordance with § 15-859 of the Insurance Article; [and]

8 (xxiv) Beginning on January 1, 2025, shall provide coverage for  
9 prostheses in accordance with § 15-844 of the Insurance Article; AND

10 (XXV) BEGINNING ON JULY 1, 2026, SHALL PROVIDE COVERAGE  
11 FOR SINGLE-GENE AND MULTIGENE PHARMACOGENOMIC TESTING IN ACCORDANCE  
12 WITH § 15-861 OF THE INSURANCE ARTICLE.

13 **Article - Insurance**

14 **15-861.**

15 (A) IN THIS SECTION, "PHARMACOGENOMIC TESTING" MEANS LABORATORY  
16 GENETIC TESTING, INCLUDING SINGLE-GENE AND MULTIGENE PANEL TESTING,  
17 CONDUCTED TO EVALUATE HOW AN INDIVIDUAL'S GENETIC PROFILE MAY IMPACT  
18 THE EFFICACY, SAFETY, OR TOXICITY OF MEDICATIONS.

19 (B) THIS SECTION APPLIES TO:

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

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

27 (C) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE FOR  
28 SINGLE-GENE AND MULTIGENE PHARMACOGENOMIC TESTING IF:

29 (1) THE PHARMACOGENOMIC TESTING IS ORDERED BY A TREATING  
30 PROVIDER FOR AN INSURED OR ENROLLEE WITH A DIAGNOSIS OF DEPRESSION OR  
31 ANXIETY; AND

1           **(2) THE TREATING PROVIDER IS CONSIDERING A MEDICATION**  
2 **CHANGE, DOSE ADJUSTMENT, OR AUGMENTATION AND THE MEDICATION UNDER**  
3 **CONSIDERATION HAS A KNOWN GENE-DRUG INTERACTION.**

4           **(D) A PRIOR AUTHORIZATION REQUIREMENT IMPOSED FOR COVERAGE**  
5 **REQUIRED UNDER THIS SECTION:**

6           **(1) SHALL PROVIDE A CLEAR AND MEANINGFUL PATHWAY FOR**  
7 **COVERAGE THAT ENSURES TIMELY ACCESS TO THE COVERAGE REQUIRED UNDER**  
8 **SUBSECTION (C) OF THIS SECTION;**

9           **(2) SHALL REQUIRE ONLY THE MINIMUM NECESSARY**  
10 **DOCUMENTATION FROM THE TREATING PROVIDER TO DETERMINE WHETHER THE**  
11 **PATIENT MEETS THE CRITERIA FOR COVERAGE UNDER SUBSECTION (C) OF THIS**  
12 **SECTION;**

13           **(3) SHALL ALLOW A SUFFICIENT AUTHORIZATION TIME FRAME**  
14 **FOLLOWING THE COLLECTION OF A SPECIMEN FOR PHARMACOGENOMIC TESTING**  
15 **FOR THE SUBMISSION OF A PRIOR AUTHORIZATION REQUEST AND CLAIMS RELATED**  
16 **TO PHARMACOGENOMIC TESTING;**

17           **(4) SHALL ALLOW A PRIOR AUTHORIZATION REQUEST TO BE**  
18 **SUBMITTED BY A TREATING PROVIDER OR A LABORATORY PROVIDER; AND**

19           **(5) MAY NOT IMPOSE UNDUE ADMINISTRATIVE BURDENS OR DELAYS**  
20 **THAT CREATE BARRIERS TO CARE FOR AN INSURED OR ENROLLEE.**

21           **(E) (1) AN ENTITY THAT DOES NOT COMPLY WITH THIS SECTION SHALL**  
22 **BE SUBJECT TO A MONETARY PENALTY OF UP TO \$10,000 PER INSTANCE OF**  
23 **NONCOMPLIANCE AND AN ADDITIONAL PENALTY OF \$1,000 PER DAY FOR EACH DAY**  
24 **THE NONCOMPLIANCE CONTINUES AFTER NOTIFICATION OF NONCOMPLIANCE**  
25 **FROM THE COMMISSIONER TO THE ENTITY.**

26           **(2) (I) THE COMMISSIONER MAY REQUIRE AN ENTITY THAT DOES**  
27 **NOT COMPLY WITH THIS SECTION TO SUBMIT AND IMPLEMENT A CORRECTIVE**  
28 **ACTION PLAN WITHIN 30 DAYS AFTER RECEIPT OF A REQUEST FOR A CORRECTIVE**  
29 **ACTION PLAN FROM THE COMMISSIONER.**

30           **(II) FAILURE TO IMPLEMENT A CORRECTIVE ACTION PLAN**  
31 **REQUIRED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH MAY RESULT IN**  
32 **ADDITIONAL ENFORCEMENT ACTIONS.**

1                   **(3) AN ENTITY SUBJECT TO A PENALTY UNDER THIS SUBSECTION MAY**  
2 **REQUEST AN ADMINISTRATIVE HEARING UNDER TITLE 10, SUBTITLE 2 OF THE**  
3 **STATE GOVERNMENT ARTICLE.**

4           **(F) (1) THE COMMISSIONER SHALL CONDUCT PERIODIC AUDITS AND**  
5 **REVIEWS OF ENTITIES SUBJECT TO THIS SECTION TO DETERMINE COMPLIANCE**  
6 **WITH THIS SECTION.**

7                   **(2) THE COMMISSIONER SHALL ESTABLISH A PROCESS FOR**  
8 **PATIENTS, PRESCRIBERS, AND LABORATORIES TO REPORT INSTANCES OF**  
9 **NONCOMPLIANCE WITH THIS SECTION.**

10           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
11 October 1, 2025.