

**Department of Legislative Services**  
Maryland General Assembly  
2023 Session

**FISCAL AND POLICY NOTE**  
**Enrolled - Revised**

Senate Bill 805

(Senator Ellis)

Finance

Health and Government Operations

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

This bill requires insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers), beginning January 1, 2024, and Medicaid (including managed care organizations (MCOs)), beginning July 1, 2025, to 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. The Maryland Department of Health (MDH) must submit a specified report on Medicaid and biomarker testing by December 1, 2024. The Maryland Health Care Commission (MHCC) must report on the impact of providing biomarker testing by December 1, 2025. **The bill takes effect January 1, 2024; the bill’s insurance provisions apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after that date.**

**Fiscal Summary**

**State Effect:** MDH and MHCC can submit the required reports using existing budgeted resources. Medicaid expenditures (60% federal funds, 40% general funds) increase by an indeterminate but potentially significant amount beginning in FY 2026 to cover biomarker testing, as discussed below. Federal fund revenues increase accordingly. Expenditures are likely offset by indeterminate savings. Minimal special fund revenue increase for the Maryland Insurance Administration in FY 2024 only from the \$125 rate and form filing fee. Review of form filings can be handled with existing budgeted resources. There is no impact on the State Employee and Retiree Health and Welfare Benefits Program. **This bill may increase the cost of an entitlement program beginning in FY 2026.**

**Local Effect:** To the extent the mandate increases the cost of health insurance, expenditures for local governments that purchase fully insured medical plans may increase. Revenues are not affected.

**Small Business Effect:** None.

## Analysis

### Bill Summary:

#### *Coverage of Biomarker Testing*

“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 and includes gene mutations, characteristics of genes, or protein expression.

“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. “Biomarker testing” includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

Coverage of biomarker testing must include testing (1) cleared or approved by the U.S. Food and Drug Administration (FDA); (2) required or recommended for an FDA-approved drug to ensure the insured or enrollee is a good candidate for the drug treatment; (3) required or recommended through a warning or precaution for an FDA-approved drug 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, as specified.

Coverage must be provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. Coverage may be subject to the annual deductibles, copayments, or coinsurance requirements imposed by a carrier for similar coverage under the same health insurance policy or contract but may not be greater than those imposed for similar coverage.

#### *Reporting Requirements*

By December 1, 2024, MDH must report to the Governor and the General Assembly on the following:

- the fiscal impact of the biomarker testing coverage required under the bill on Medicaid's policy on biomarker testing coverage for specific cancers during fiscal 2024;
- any available data on use of biomarker testing by race and ethnicity in Medicaid;
- the anticipated fiscal and access impacts of expanding Medicaid coverage for biomarker testing in fiscal 2026, as specified under the bill;
- whether to establish a cap on the amount of reimbursement for biomarker testing coverage and, if recommended, the recommended cap amount and the anticipated fiscal and access impacts of establishing the cap; and
- recommendations on any legislative changes to the bill's requirements relating to Medicaid, including MCOs.

By December 1, 2025, MHCC must report to the Senate Finance Committee and the House Health and Government Operations Committee on the impact of providing coverage of biomarker testing, including an analysis of the impact of providing access to individuals based on race, gender, age, and public or private insurance.

**Current Law:** Under Maryland law, there are more than 50 mandated health insurance benefits that specified carriers must provide to their enrollees. The federal Patient Protection and Affordable Care Act requires nongrandfathered health plans to cover 10 essential health benefits (EHBs), which include items and services in the following categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including dental and vision care.

Under § 31-116 of the Maryland Insurance Article, EHBs must be included in the State benchmark plan and, notwithstanding any other benefits mandated by State law, must be the benefits required in (1) all individual health benefit plans and health benefit plans offered to small employers (except for grandfathered health plans) offered outside the Maryland Health Benefit Exchange (MHBE) and (2) all qualified health plans offered in MHBE.

**State Fiscal Effect:** MDH advises that it is in the process of implementing Medicaid coverage of biomarker testing for cancer treatment when used to determine if a specific medication or therapy will be more effective in treatment, thereby guiding clinical management. MDH will cover tests that are FDA-approved, approved by Medicare, and meet specific National Comprehensive Cancer Network cancer guidelines. The testing

facility must meet Clinical Laboratory Improvement Amendments Standards, and the companion drug or therapy must be approved by FDA and Medicare.

Under the bill, beginning July 1, 2025, Medicaid, subject to the limitations of the State budget and as permitted by federal law, must provide coverage for biomarker testing for all diseases and conditions (if the use of the testing is supported by medical and scientific evidence), including autoimmune diseases, cardiovascular diseases, kidney diseases, infectious diseases, metabolic diseases, and behavioral health. As many of these diseases and conditions are prevalent in the Medicaid population, and an individual may require more than one biomarker test for certain diseases or conditions or need tests for more than one disease or condition in a year, MDH anticipates a significant fiscal impact.

*For illustrative purposes only*, as of December 2022, there were 1,586,005 Medicaid enrollees. Should 1% of enrollees receive one biomarker test at a cost of \$1,700 per test, Medicaid expenditures increase by almost \$27.0 million on an annual basis. MDH advises that uptake of biomarker testing could be as high as 25% of Medicaid enrollees (at an estimated total annual cost of \$429.6 million) and that 10% of Medicaid enrollees younger than age 18 with an emergency department visit will receive a biomarker test (at an estimated total annual cost of \$30.6 million).

The Department of Legislative Services notes that coverage of biomarker testing is likely offset by savings (or cost avoidance) as the tests are intended to diagnose, treat, and manage diseases and conditions; facilitate the use of more effective and targeted health care treatments; and help avoid use of therapies that may be unsafe or ineffective for specific patients. However, any such savings and, thus, the net impact on Medicaid expenditures cannot be reliably estimated at this time.

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### **Additional Information**

**Prior Introductions:** Similar legislation has not been introduced within the last three years.

**Designated Cross File:** HB 1217 (Delegate Toles, *et al.*) - Health and Government Operations.

**Information Source(s):** Department of Budget and Management; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

**Fiscal Note History:**  
rh/ljm

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