Department of Legislative Services

Maryland General Assembly
2025 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 961 (Senator Mautz)
Finance

Maryland Medical Assistance Program and Health Insurance - Pharmacogenomic Testing - Required Coverage

This bill requires certain insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers), beginning October 1, 2025, to provide coverage for single-gene and multigene "pharmacogenomic testing" under specified circumstances. Beginning July 1, 2026, Medicaid, including managed care organizations (MCOs), must provide the same coverage. The bill limits the prior authorization requirements that may be applied to pharmacogenomic testing and establishes monetary penalties for noncompliance by carriers and MCOs. The Insurance Commissioner and the Maryland Department of Health (MDH) must ensure compliance and establish a process for patients, prescribers, and laboratories to report instances of noncompliance.

Fiscal Summary

State Effect: Minimal increase in special fund revenues for the Maryland Insurance Administration (MIA) in FY 2026 only from the $125 rate and form filing fee. Any additional workload on MIA can likely be handled with existing resources. As Medicaid and the State Employee and Retiree Health and Welfare Benefits Program generally cover pharmacogenomic testing, there is likely no material impact on State agencies. Potential minimal increase in general fund revenues from penalties beginning in FY 2026.

Local Effect: Potential increase in health insurance costs for local governments that purchase fully insured plans to the extent such testing is not already covered. Revenues are not affected.

Small Business Effect: None.

Analysis

Bill Summary:

Mandated Coverage of Pharmacogenomic Testing

"Pharmacogenomic testing" means laboratory genetic testing, including single-gene and multigene panel testing, conducted to evaluate how an individual's genetic profile may impact the efficacy, safety, or toxicity of medications. Coverage must be provided if (1) pharmacogenomic testing is ordered by a treating provider for an insured or enrollee with a diagnosis of depression or anxiety and (2) the treating provider is considering a medication change, dose adjustment, or augmentation and the medication under consideration has a known gene-drug interaction.

Limitation on Prior Authorization Requirements

A prior authorization requirement imposed for coverage of pharmacogenomic testing must (1) provide a clear and meaningful pathway for coverage that ensures timely access to coverage; (2) require only the minimum necessary documentation from the treating provider to determine whether the patient meets criteria for coverage; (3) allow a sufficient authorization timeframe following the collection of a specimen for the submission of a prior authorization request and claims; and (4) allow a prior authorization request to be submitted by a treating provider or a laboratory. A prior authorization requirement may not impose undue administrative burdens or delays that create barriers to care.

Enforcement and Monetary Penalties for Noncompliance

The Commissioner must conduct periodic audits and reviews of carriers to determine compliance and establish a process for patients, prescribers, and laboratories to report instances of noncompliance.

A carrier that does not comply with the bill is subject to a monetary penalty of up to $10,000 per instance and an additional penalty of up to $1,000 per day that the noncompliance continues after notification from the Commissioner. The Commissioner may require a noncompliant carrier to submit and implement a corrective action plan within 30 days of receipt of a request from the Commissioner. Failure to implement a corrective action plan may result in additional enforcement actions. A carrier subject to a penalty may request an administrative hearing under the Administrative Procedure Act.

Medicaid

Beginning July 1, 2026, Medicaid, including MCOs, must provide the same coverage of pharmacogenomic testing in the same manner as carriers. MDH must conduct periodic audits and reviews of MCOs to determine compliance and establish a process for patients, prescribers, and laboratories to report instances of noncompliance. An MCO that does not comply with the bill is subject to the same monetary penalties as a carrier and the requirement to submit a corrective action plan, to be imposed by MDH rather than the Commissioner. An MCO subject to a penalty may request an administrative hearing under the Administrative Procedure Act.

Current Law: Under Maryland law, there are more than 50 mandated health insurance benefits that specified carriers must provide. 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, not withstanding 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.

Carriers, effective January 1, 2024, and Medicaid (including MCOs), beginning July 1, 2025, must 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. "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. Coverage of biomarker testing must include, among other things, testing that is required or recommended through a warning or precaution for an U.S. Food and Drug Administration-approved drug to identify whether an insured or enrollee will have an adverse reaction.

Under current Medicaid regulations (COMAR 10.67.09.04), any Medicaid MCO that implements prior authorization must make a determination within 2 business days of receipt of necessary clinical information, but no later than 14 calendar days from the date of the initial request. For expedited authorization decisions, the MCO must make a determination and provide notice no later than 72 hours after receipt of the request for service if the provider indicates or the MCO determines that the standard timeframe could jeopardize the patient's life, health, or ability to attain, maintain, or regain maximum function.

State Fiscal Effect:

Penalties

A carrier or MCO that does not comply with the bill is subject to a monetary penalty of up to $10,000 per instance and an additional penalty of up to $1,000 per day that the noncompliance continues after notification from the Insurance Commissioner or MDH, respectively. To the extent a carrier or MCO fails to comply, general fund revenues increase by an indeterminate but likely minimal amount beginning as early as fiscal 2026.

Medicaid

MDH estimates that 12 of the 63 medications for which pharmacogenetic testing is available are impacted by this bill – all of which are currently covered by Medicaid. In calendar 2023, 2,709 pharmacogenomic tests were provided to 1,567 Medicaid participants. MDH does not require prior authorization for testing for fee-for-service Medicaid participants; however, prior authorization is required by MCOs. As MDH assumes the current prior authorization process for MCOs complies with the bill's limitations and pharmacogenomic testing is currently covered by Medicaid, there is likely no material impact on Medicaid under the bill.

This analysis assumes that MDH can ensure MCO compliance with the bill through existing audits and reviews; review corrective action plans; impose penalties; and establish a process for patients, prescribers, and laboratories to report instance of noncompliance using existing budgeted resources.

State Employee and Retiree Health and Welfare Benefits Program

The State Employee and Retiree Health and Welfare Benefits Program is largely self-insured for its medical contracts and, as such, except for the one fully insured integrated health model medical plan (Kaiser), is exempt from most State health insurance

mandates. However, the program generally provides coverage as otherwise required under State law.

The Department of Budget and Management (DBM) advises that pharmacogenomic testing is generally covered under the program when recommended by a treating provider after prior authorization. In calendar 2024, the program covered 2,262 total pharmacogenomic tests with potential use for depression or anxiety at an average cost per test of $225. Thus, there is likely no material impact on the program under the bill.

DBM notes that there is some potential for increased utilization of pharmacogenomic testing under the bill. Alternatively, there is also potential for decreased spending based on avoiding waste and adverse events through identification of responders and nonresponders to medications and optimizing drug dose.

Maryland Insurance Administration

MIA advises that it can likely conduct periodic audits and reviews of carriers to determine compliance; review corrective action plans; impose penalties; and establish a process for patients, prescribers, and laboratories to report instances of noncompliance using existing budgeted resources.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the past three years.

Designated Cross File: None.

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

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