Department of Legislative Services

Maryland General Assembly
2026 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 608 (Senator Mautz)
Finance

Maryland Medical Assistance Plan 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, 2026, to provide coverage for single-gene and multigene "pharmacogenomic testing" under specified circumstances. Beginning July 1, 2027, 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 2027 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 2027.

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, 2027, 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. Carriers 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.

The federal Patient Protection and Affordable Care Act (ACA) 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.

For additional information on mandated health insurance benefits in Maryland, please see the **Appendix – Mandated Health Insurance Benefits**.

Under 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 2027.

Medicaid

MDH advises that Medicaid currently covers pharmacogenetic testing. In calendar 2024, 1,709 pharmacogenomic tests were provided to 1,075 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.

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 2025, the program covered 1,967 total pharmacogenomic tests with potential use for depression or anxiety at an average cost per test of $209. 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 Comments: MIA advises that the bill does not apply to the nongrandfathered individual and small employer markets. Should the bill be amended to apply to all markets, the State would be required to defray the cost of the new mandate to the extent it applies to the individual and small group ACA plans.

Additional Information

Recent Prior Introductions: Similar legislation has been introduced within the last three years. See SB 961 of 2025.

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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caw/ljm

Analysis by: Jennifer B. Chasse

Direct Inquiries to:
(410) 946-5510
(301) 970-5510

Appendix – Mandated Health Insurance Benefits

Overview

Fully insured, large group plans and certain individual plans must cover Maryland's mandated health insurance benefits. These mandates do not apply to most individual or small group plans, public health insurance, or plans issued outside of Maryland. However, individual and small group plans and plans sold through the Maryland Health Benefit Exchange (MHBE) must cover federal essential health benefits (EHBs). Thus, the type of plan an individual is enrolled in generally determines which benefits must be provided.

Most Marylanders Are Insured by Employment-based Coverage

Maryland residents generally obtain health insurance from one of three sources: (1) employment-based coverage; (2) private coverage in the individual market; or (3) public health insurance provided by the State and/or federal government (*i.e.*, Medicaid, the Maryland Children's Health Program (MCHP), Medicare, and military-related coverage). In calendar 2023 (the most recent data available), more than one-half (53.9%) of the State's population had employment-based coverage, more than one-third (34.1%) were covered by public health insurance programs, and 5.7% purchased coverage in the individual market. The remaining 6.5% of Marylanders were uninsured.

State Regulation of Insurance Applies Only to Certain Plans

Employment-based coverage is either fully insured or self-insured. A fully insured plan is a traditional model for health insurance under which an employer pays a fixed premium to an insurer and the insurer assumes all financial risk and responsibility for paying claims. Fully insured plans are most common among small to mid-sized businesses as they offer more predictable costs and less administrative burden. In a self-insured plan, the employer assumes all financial risk and pays claims directly, usually through a third-party administrator. Self-insured plans are more common among larger employers with the resources to assume the financial risk.

The federal Employee Retirement Income Security Act preempts states' ability to require private employers to offer health insurance coverage and exempts self-insured plans from state insurance regulation. As a result, only fully insured plans are regulated by state insurance regulators. Thus, in Maryland, self-insured plans are not regulated by the Maryland Insurance Administration (MIA) and are not subject to Maryland law.

In calendar 2024, 2.58 million Maryland residents younger than age 65 were insured through commercial health benefit plans, of which 890,245 were covered by a fully insured

plan and 1.69 million were covered by a self-insured plan. Thus, only about one-third (34.5%) of those covered through commercial plans were in fully insured plans subject to State regulation. Overall, only 17.4% of the State's nonelderly population was covered by a plan subject to State regulation.

Mandated Benefits Apply Only to Large Group and Grandfathered Plans

Maryland law requires insurers, health maintenance organizations, and nonprofit health service plans to cover more than 50 specific benefits. These "mandated benefits" apply to expense-incurred contracts that provide "hospital, medical, and surgical benefits," which include non-major medical products and federally excepted benefits (benefits outside of primary medical coverage that are not subject to certain federal requirements). These include fully insured, large group plans (≥50 employees), individual grandfathered plans in effect on or before March 23, 2010, when the federal Patient Protection and Affordable Care Act (ACA) was enacted, and limited or specialty plans such as fixed-indemnity plans. Maryland's State Employee and Retiree Health and Welfare Benefits Program is predominately self-insured and thus largely exempt from mandated benefits. However, the program generally provides coverage for these benefits as otherwise required under State law.

Mandated benefits *could* apply to individual and small group policies. However, if the benefits go beyond those in the State benchmark plan (a reference plan that defines the minimum benefits that must be offered in the individual and small group markets in Maryland), the State must cover the cost. Thus, mandated benefits are not typically applied to those policies.

Mandated benefits do not apply to Medicaid/MCHP, Medicare, the Federal Employees Health Benefits Program, or military/Veterans Administration coverage. Mandated benefits also do not apply to health benefit plans issued outside of Maryland – such as when a Maryland resident works for an employer based in another state and the plan is issued in that state. In that instance, the plan is subject to the requirements (and mandated benefits) of the state in which it is issued.

Exhibit 1 summarizes mandated benefits for large group and grandfathered plans. For further specifics on mandated benefits, see Title 15, Subtitle 8 of the Insurance Article.

Exhibit 1
Maryland's Mandated Health Insurance Benefits for Large Group and Grandfathered Plans

- Amino-acid elemental formula
- Anesthesia for dental care
- Biomarker testing
- Blood products
- Breast cancer screening
- Breast prosthesis following a mastectomy
- Child well visits and immunizations
- Chlamydia screening
- Cleft lip/palate treatment/management
- Clinical trials
- Colorectal cancer screening
- Contraceptive drugs or devices
- Diabetic equipment or supplies
- Emergency room services
- Fertility awareness-based methods
- Fertility preservation due to medical treatment that may cause infertility
- Gynecological care
- Habilitative services
- Hair prosthesis following cancer
- Hearing aids
- Home health care
- Human papilloma virus screening
- Infertility benefits (including IVF)
- Inpatient hospital services
- Laboratory services
- Lung cancer screening
- Lymphedema diagnosis, evaluation, and treatment
- Male sterilization
- Mastectomies
- Medical foods
- Mental health and substance use treatment
- Morbid obesity surgical treatment
- Osteoporosis prevention and treatment
- Ostomy equipment and supplies
- Physician services
- Pregnancy and maternity benefits
- Prescription benefits
- Preventive services
- Prosthetic devices
- Prostate cancer screening
- Reconstructive breast surgery
- Referrals to specialists
- Second opinions and coverage of outpatient services
- Smoking cessation
- Surgical removal of testicles
- Temporo-Mandibular Joint Syndrome treatment
- X-rays

IVF: in vitro fertilization

Note: Mandated benefits as of January 2025. Coverage of calcium score testing is required beginning January 1, 2026.

Source: Maryland Insurance Administration; Department of Legislative Services

Application of Mandated Benefits in Practice

Legislation is frequently introduced to add new mandated benefits. For example, Senate Bill 518 of 2025 would have required coverage for preventive screenings for ovarian cancer for individuals aged 45 and older. The bill would have applied only to commercial health insurance, specifically fully insured large group plans and individual grandfathered plans. Coverage would not have applied to self-insured plans, nongrandfathered individual or small group plans, plans issued in another state to a Maryland resident, or any public health insurance program (in the same way that current mandated benefits do not apply to these plans).

Essential Health Benefits Apply to Individual and Small Group Plans

The ACA requires nongrandfathered health plans to cover 10 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; (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.

Maryland law requires that EHBs be included in the State benchmark plan and in all qualified health plans offered through MHBE. **Exhibit 2** summarizes the EHBs required as of September 2025. For further specifics, see MIA's *Essential Health Benefits Chart: Individual and Small Group Plans*.

Exhibit 2
Essential Health Benefits for Individual and Small Group Plans

- Allergy serum
- Ambulance service
- Bariatric surgery
- Blood and blood products
- Breast reconstructive surgery/prosthesis
- Cardiac rehabilitation
- Care in office for illness or injury
- Case management
- Chiropractic services
- Controlled clinical trials
- Diabetic treatment/equipment/supplies
- Durable medical equipment
- Emergency services
- Family planning services
- General anesthesia/associated care for dental care for children
- Habilitative services
- Hair prosthesis following cancer
- Hearing aids
- Home health care
- Hospice
- Infertility services (excludes IVF)
- Inpatient hospital services
- Medical food
- Mental health and substance use benefits
- Nutritional services
- Outpatient hospital services
- Outpatient laboratory/diagnostic services
- Outpatient short-term rehabilitation
- Patient centered medical homes
- Pediatric dental
- Pediatric vision
- Pregnancy and maternity
- Prescription drugs
- Preventive services
- Prostate cancer screening
- Pulmonary rehabilitation
- Skilled nursing facility
- Transplants
- Wellness benefits

IVF: in vitro fertilization

Note: Essential health benefits as of September 2025.

Source: Maryland Insurance Administration; Department of Legislative Services