

Department of Legislative Services
Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 188

(Senator Lam, *et al.*)

Finance

Health and Government Operations

Public Health - Rare Disease Advisory Council

This bill establishes a Rare Disease Advisory Council to enhance research and provide policy recommendations on matters related to individuals living with rare diseases in the State. The council's general duties include (1) performing a survey to establish the needs of rare disease patients, caregivers, and health care providers in the State; (2) developing policy recommendations; (3) creating a publicly accessible webpage; (4) providing an annual report to the Governor and the General Assembly; and (5) providing recommendations to address the needs of individuals living with rare diseases in the State. The Maryland Department of Health (MDH) must staff the council. Members may not receive compensation but are entitled to reimbursement for travel expenses under the standard State travel regulations.

Fiscal Summary

State Effect: MDH can staff and additional State agencies can participate in the council using existing budgeted resources. To the extent the council receives federal grant funding, federal fund revenues and expenditures increase by an indeterminate amount.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary:

Council Membership

The council comprises (1) one member of the Senate, appointed by the President of the Senate; (2) one member of the House of Delegates, appointed by the Speaker of the House; (3) the Secretary of Health (or designee); (4) the chair of the State Advisory Council on Hereditary and Congenital Disorders (or designee); (5) one representative of the Office of Minority Health and Health Disparities (or designee), designated by the director of the office; (6) one representative of Maryland Medicaid, designated by the Secretary; (7) one representative of the Maryland Insurance Administration, designated by the Maryland Insurance Commissioner; and (8) 14 members appointed by the Governor.

Gubernatorial appointees include: (1) one representative of an academic research institution that receives rare disease grant funding; (2) one geneticist licensed and practicing in the State; (3) one registered nurse or advanced practice nurse licensed and practicing in the State with experience treating rare diseases; (4) one physician licensed in the State with experience treating rare diseases; (5) one hospital administrator (or designee) from a Maryland hospital that provides care to individuals with rare diseases; (6) one pharmacist licensed in the State with experience dispensing drugs used to treat rare diseases; (7) two individuals diagnosed with a rare disease; (8) one caregiver of an individual with a rare disease; (9) one representative of a rare disease patient organization in the State; (10) one representative of the biopharmaceutical industry; (11) one representative of a health insurance carrier providing coverage in the State; (12) one member of the scientific community who is engaged in rare disease research, and (13) one representative of an organization that provides care management for individuals enrolled in the Medicaid Rare and Expensive Case Management Program.

Members of the council must be full-time residents of the State.

Council Duties

The initial meeting of the council must occur by December 30, 2024. Until October 1, 2025, the council must meet at least once per month in person or through an online meeting platform. After October 1, 2025, the council must meet at least once per quarter in person or through an online meeting platform.

Policy Assessment and Development

In the first year, the council must convene public hearings, make inquiries, and solicit comments from the public to develop a survey assessing the needs of individuals living with rare diseases, their caregivers, and health care providers in the State.

The council must also (1) consult with experts on rare diseases to develop policy recommendations, as specified; (2) research and make recommendations to State agencies and insurers on the impact of specified utilization management procedures on the provision of treatment and care for patients; (3) establish best practices and protocols to include in State planning related to natural disasters and public health emergencies or other emergency declarations, as specified; (4) evaluate and make recommendations regarding coverage or prescription drugs for rare disease patients, as specified; (5) publish a list of existing and publicly accessible resources, as specified; (6) identify areas of unmet needs for research that can inform future studies and reports by the council; (7) identify and distribute educational resources for health care providers to foster recognition and optimize treatment of rare diseases in the State; and (8) research and identify best practices to ensure continuity of care for individuals living with rare diseases transitioning from pediatric to adult care.

The council must provide opportunities for the public to hear updates and provide input on council activities. The council must maintain a webpage to provide a list of resources and facilitate public communication regarding the council's activities, including meeting minutes and notices of upcoming meetings, and the ability to submit public comments.

Reporting

By December 1, 2024, and annually thereafter, the council must submit a report to the Governor and the General Assembly. The report must describe the council's activities and funding sources (including grants that were applied for and accepted and the remaining balances of any current grants), as well as provide recommendations on ways to address the needs of individuals living with rare diseases in the State.

Council Funding

The council may solicit funds by applying for federal or State grants. The council must establish a method to securely hold and distribute funds to support its duties.

Current Law: COMAR 10.10.01.03, which governs medical laboratory testing, defines "rare disease" as (1) a disabling, chronically debilitating, or life-threatening disease or condition that has fewer than 200,000 affected individuals in the United States, which is equivalent to a prevalence of fewer than 1 individual per 2,000 individuals in the population

or an incidence of fewer than 1 in 10,000; (2) a disabling or life-threatening disease or condition that is listed as a rare disease by the National Institutes of Health Office of Rare Diseases; or (3) a disabling or life-threatening disease or condition in which more than 200,000 individuals are affected if a subpopulation of the disease or condition is equal to a prevalence of fewer than 1 individual per 2,000 or the incidence of the disease or condition is fewer than 5 in 10,000 in a defined community.

Additional Comments: The Genetic and Rare Diseases Information Center estimates that more than 7,000 rare diseases affect 25 million to 30 million Americans. Risk factors are often genetic. Rare diseases include conditions impairing a person's physical or mental ability and many are life-threatening. According to the National Organization for Rare Disorders, 20 states have a rare disease advisory council.

Additional Information

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

Designated Cross File: HB 302 (Delegate Shetty, *et al.*) - Health and Government Operations.

Information Source(s): University System of Maryland; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

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