



Senate Fiscal Agency
P.O. Box 30036
Lansing, Michigan 48909-7536



Telephone: (517) 373-5383
Fax: (517) 373-1986

House Bill 4654 (Substitute H-3 as passed by the House)
Sponsor: Representative Cara Clemente
House Committee: Health Policy
Senate Committee: Health Policy and Human Services

Date Completed: 2-23-22

CONTENT

The bill would amend Chapter 5 (Prevention and Control of Diseases and Disabilities) of the Public Health Code to create the Rare Disease Advisory Council within the Department of Health and Human Services (DHHS), and to prescribe its membership and duties.

The bill would take effect 90 days after its enactment.

Council

Specifically, the bill would create the Rare Disease Advisory Council within the DHHS for the purpose of advising the Department and other State agencies on research, diagnosis, and treatment efforts related to rare diseases in the State. "Rare disease" would mean a disease that affects fewer than 200,000 individuals in the United States.

Membership

Under the bill, the Council would consist of the Director of the DHHS or his or her designee, one member appointed by the Governor, and all of the following members appointed by the Director:

- One physician licensed under Part 170 (Medicine) or 175 (Osteopathic Medicine and Surgery) of the Code who had experience treating patients with rare diseases.
- One registered professional nurse licensed under Part 172 (Nursing) of the Code who had expertise in providing care to patients with rare diseases.
- An epidemiologist who practiced in Michigan who had expertise in the incidence, prevalence, and control of rare diseases.
- Two individuals who represented hospitals located in Michigan, at least one of whom represented a hospital that conducted research; each individual would have to represent a different hospital.
- One individual representing a health insurer.
- One individual representing a health maintenance organization.
- Two individuals representing the biopharmaceutical industry.
- Two individuals who engage in rare disease research.
- One member selected from a list of nominees submitted by the Speaker of the House of Representatives.
- One member selected from a list of nominees submitted by the Senate Majority Leader.
- Three parents of children with a rare disease; each parent would have to be from a different family.
- Three individuals with a rare disease; each individual would have to have a different rare disease.

- Two individuals representing rare disease patient organizations that operated in Michigan; each individual would have to represent a different organization.
- A medical ethicist who practiced in Michigan.
- A representative from the national pharmaceutical industry or a pharmaceutical company working in the area of rare diseases.
- A genetic counselor licensed under Part 170 who was familiar with rare diseases.

The Director could appoint additional members to the Council that he or she considered necessary or appropriate.

The members first appointed to the Council would have to be appointed within 90 days after the bill's effective date. Council members would serve for four-year terms or until a successor was appointed, whichever was later. A vacancy on the Council would have to be filled in the same manner as the original appointment. An individual appointed to fill a vacancy created other than by expiration of a term would have to be appointed for the unexpired term of the member whom he or she was succeeding in the same manner as the original appointment. The Director could remove a Council member for incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

A member of the Council would not be entitled to compensation for service on the Council, but the Council could reimburse a member for actual and necessary expenses incurred in serving.

At any time, the Council could make recommendations to the Director on the appointment of additional members to the Council that the Council considered necessary to carry out its duties.

Meetings

The bill would require the Director to call the first meeting of the Council. At that meeting, the Council would have to elect from among its members a chairperson and could elect other officers as it considered necessary or appropriate. The Council would have to meet at least quarterly, or more frequently at the call of the chairperson or at the request of four or more members.

A majority of the Council members would constitute a quorum for the transaction of business, and a majority of the members present and serving would be required for official action of the Council. The Council would be subject to the Open Meetings Act and the Freedom of Information Act.

Duties & Responsibilities

The bill would require the Council to do all of the following:

- Research and identify priorities relating to the cost-effectiveness of and access to treatments and services provided to individuals with rare diseases in Michigan, and develop policy recommendations aimed at preventing discrimination against individuals with rare diseases with respect to the cost-effectiveness of and access to treatments and services and other related issues.
- Identify best practices for rare diseases from other states and at the national level that could improve the education, care, and treatment of, and services and supports provided to, adults and minors with rare diseases in Michigan.
- Coordinate with other rare disease advisory bodies, community-based organizations, and other public and private organizations in performing its duties to ensure greater

- cooperation between Michigan, other states, and the Federal government regarding the research, diagnosis, and treatment of rare diseases, by disseminating the Council's research, findings, and recommendations when appropriate.
- Serve as an advisory body on rare diseases to the Legislature, the Governor, the DHHS, and other State agencies.
- Research and make recommendations to the Legislature and the DHHS on the most appropriate method to collect data on rare diseases.
- Provide information or advice on rare diseases to the DHHS or Governor, as the Director or Governor considered necessary or appropriate.
- By December 21, 2022, develop a list of rare diseases and post the list on the DHHS's website; the Council would have to review and update the list every two years and post the updated list on its website.
- Annually select one rare disease from the list described above, investigate the rare disease, and make recommendations to the Legislature on the rare disease.
- Beginning December 21, 2022, and by December 21 of every other year beginning after the first report was submitted to the Legislature, submit a written report to the Legislature on the Council's activities, findings, and recommendations.

The Council also could do one or more of the following:

- Hold public hearings and make inquiries and receive comments from the general public to assist the Council in developing recommendations.
- Consult with experts on rare diseases to assist the Council in developing recommendations, including experts from the private sector, organized labor groups, government agencies, and institutions of higher education.
- Apply for and accept grants and gifts from government and private sources.

The DHHS would have to provide clerical and administrative assistance to the Council in applying for grants, as the Director considered necessary or appropriate.

Any findings and recommendations made by the Council would have to be based on medical or scientific evidence.

Proposed MCL 333.5135 & 333.5135a

Legislative Analyst: Stephen Jackson

FISCAL IMPACT

The bill would have an indeterminate negative fiscal impact on the DHHS and no impact on local units of government. The Department would incur the costs for staff or support provided to the Rare Disease Advisory Council. Members of the Council would serve without compensation; however, they could be reimbursed for actual and necessary expenses incurred while serving.

The typical annual costs to support an advisory council can range from \$10,000 to \$200,000 depending on the travel expenses and staff demands of the Council. Public Act 87 of 2021, included \$70,000 General Fund/General Purpose to support the efforts of the Council. This funding was continued in the Governor's Fiscal Year 2022-23 Budget Recommendation for the Department.

Fiscal Analyst: Eilyn Ackerman

SAS\S2122\s4654sa

This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.