

# Legislative Analysis



## RARE DISEASE ADVISORY COUNCIL

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<http://www.house.mi.gov/hfa>

### House Bill 4654 (H-3) as reported from committee

**Sponsor: Rep. Cara Clemente**

**Committee: Health Policy**

**Complete to 2-4-22**

Analysis available at  
<http://www.legislature.mi.gov>

## SUMMARY:

House Bill 4654 would add two sections to Article 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). The council would exist for the purpose of advising DHHS and other state agencies on research, diagnosis, and treatment efforts related to *rare diseases* in Michigan.

*Rare disease* would mean a disease or condition that affects fewer than 200,000 individuals in the United States.

Council members would include the DHHS director or a designee, one member appointed by the governor, and all of the following members appointed by the DHHS director:

- A licensed physician (either an M.D. or D.O.) who has experience treating patients with rare diseases.
- A registered professional nurse who has expertise in providing care to patients with rare diseases.
- An epidemiologist who practices in Michigan and has experience in the incidence, prevalence, and control of rare diseases.
- Two individuals who represent two different hospitals located in Michigan, at least one of whom represents a hospital that conducts research.
- An individual who represents a health insurer.
- An individual who represents a health maintenance organization.
- Two individuals who represent the biopharmaceutical industry.
- Two individuals who engage in rare disease research.
- A member selected from a list of nominees submitted by the Speaker of the House.
- A member selected from a list of nominees submitted by the Senate Majority Leader.
- Three parents of children with a rare disease. (The parents would all have to be from different families.)
- Three individuals with three different rare diseases.
- Two individuals who represent two different rare disease patient organizations in Michigan.
- A medical ethicist who practices in Michigan.
- A representative from the national pharmaceutical industry or a pharmaceutical company working in the area of rare diseases.
- A licensed genetic counselor who is familiar with rare diseases.

Additionally, upon recommendation from the council, the DHHS director could appoint additional members that the director considers necessary or appropriate.

The governor and DHHS director would have to appoint the initial members within 90 days of the bill's effective date. Members would serve for four-year terms or until appointment of a successor, whichever is later, and vacancies would be filled in the same way as that position was filled originally. The DHHS director could remove members for incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

After the DHHS director called the initial meeting, members would elect a chairperson and could elect other officers. The council would meet at least quarterly thereafter. Meetings would have to be held in compliance with the Open Meetings Act, and council documents would have to be made available to the public in compliance with the Freedom of Information Act (FOIA). Members would serve without compensation but could be reimbursed for actual and necessary expenses.

The council could do one or more of the following:

- Apply for and accept grants and gifts from government and private sources. (DHHS would provide assistance in applying as the DHHS director determined necessary and appropriate.)
- 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 in developing recommendations.

The council would have 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 those individuals 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 and 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, DHHS, and other state agencies.
- Research and make recommendations to the legislature and DHHS on the most appropriate method to collect data on rare diseases.
- Provide information or advice on rare diseases to DHHS or the governor as needed.
- By December 21, 2022, and every two years thereafter, develop or review a list of rare diseases and post it on DHHS's website.
- Annually select one rare disease from that list, investigate the disease, and make recommendations to the legislature on the disease.
- By December 21, 2022, and yearly thereafter, submit a report to the legislature on its activities, findings, and recommendations.

Any findings or recommendations made by the council under the bill would have to be based on medical or scientific evidence.

The bill would take effect 90 days after its enactment.

Proposed MCL 333.5135 and 333.5135a

**FISCAL IMPACT:**

House Bill 4654 has fiscal cost implications of approximately \$100,000 to \$200,000 annually for DHHS. The bill requires DHHS to establish and support a new Rare Disease Advisory Council, with responsibility to investigate rare disease costs, access, and best practices, hold public hearings, consult with experts, seek grants, and annually report to the legislature on findings and recommendations. The cost to DHHS would be partly dependent on the activity level of the committee, which is required to meet at least quarterly. Members would not be compensated but could be reimbursed for expenses.

The Fiscal Year 2020-21 DHHS budget included a new appropriation of \$70,000 GF/GP and boilerplate to support a similar rare disease review committee. The funding is continued in the recently enacted FY 2021-22 DHHS budget, 2021 PA 87, and related boilerplate section 1240 is revised to support the Rare Disease Advisory Council.

The bill would have no fiscal impact on local units of government.

**POSITIONS:**

Representatives of the following entities testified in support of the bill (5-13-21):

- National Organization for Rare Disorders
- Sickle Cell of Michigan
- National Homocystinuria
- Blue Cross Blue Shield Michigan

The following entities indicated support for the bill:

- The Bonnell Foundation (10-14-21)
- MichBio (5-13-21)
- Immune Deficiency Foundation (10-14-21)
- MITO Action (10-14-21)
- Michigan Council for Maternal and Child Health (10-14-21)
- American Behcet’s Disease Association (10-14-21)

Us Against the Media indicated opposition to the bill. (10-14-21)

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations and does not constitute an official statement of legislative intent.