

**SUBSTITUTE FOR
HOUSE BILL NO. 4654**

A bill to amend 1978 PA 368, entitled
"Public health code,"
(MCL 333.1101 to 333.25211) by adding sections 5135 and 5135a.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 **Sec. 5135. (1) The rare disease advisory council is created**
2 **within the department for the purpose of advising the department**
3 **and other state agencies on research, diagnosis, and treatment**
4 **efforts related to rare diseases in this state.**

5 **(2) The council must consist of the following members:**

6 **(a) The director or his or her designee.**

7 **(b) All of the following appointed by the director:**

8 **(i) One physician licensed under part 170 or 175 who has**
9 **experience treating patients with rare diseases.**



1 (ii) One registered professional nurse licensed under part 172
2 who has expertise in providing care to patients with rare diseases.

3 (iii) An epidemiologist who practices in this state who has
4 expertise in the incidence, prevalence, and control of rare
5 diseases.

6 (iv) Two individuals who represent hospitals located in this
7 state, at least 1 of whom represents a hospital that conducts
8 research. Each individual appointed under this subparagraph must
9 represent a different hospital.

10 (v) One individual representing a health insurer.

11 (vi) One individual representing a health maintenance
12 organization.

13 (vii) Two individuals representing the biopharmaceutical
14 industry.

15 (viii) Two individuals who engage in rare disease research.

16 (ix) One member selected from a list of nominees submitted by
17 the speaker of the house of representatives.

18 (x) One member selected from a list of nominees submitted by
19 the senate majority leader.

20 (xi) Three parents of children with a rare disease. Each parent
21 appointed under this subparagraph must be from a different family.

22 (xii) Three individuals with a rare disease. Each individual
23 appointed under this subparagraph must have a different rare
24 disease.

25 (xiii) Two individuals representing rare disease patient
26 organizations that operate in this state. Each individual appointed
27 under this subparagraph must represent a different organization.

28 (xiv) A medical ethicist who practices in this state.



1 (xv) A representative from the national pharmaceutical industry
2 or a pharmaceutical company working in the area of rare diseases.

3 (xvi) A genetic counselor licensed under part 170 who is
4 familiar with rare diseases.

5 (c) One member appointed by the governor.

6 (3) Subject to subsection (13), the director may appoint
7 additional members to the council that the director considers
8 necessary or appropriate.

9 (4) The members first appointed to the council must be
10 appointed within 90 days after the effective date of the amendatory
11 act that added this section.

12 (5) Members of the council serve for terms of 4 years or until
13 a successor is appointed, whichever is later.

14 (6) A vacancy on the council must be filled in the same manner
15 as the original appointment. An individual appointed to fill a
16 vacancy created other than by expiration of a term must be
17 appointed for the unexpired term of the member whom he or she is to
18 succeed in the same manner as the original appointment.

19 (7) The director may remove a member of the council for
20 incompetence, dereliction of duty, malfeasance, misfeasance, or
21 nonfeasance in office, or any other good cause.

22 (8) The director shall call the first meeting of the council.
23 At the first meeting, the council shall elect from among its
24 members a chairperson and may elect other officers as it considers
25 necessary or appropriate. The council shall meet at least
26 quarterly, or more frequently at the call of the chairperson or at
27 the request of 4 or more members.

28 (9) A majority of the members of the council constitute a
29 quorum for the transaction of business. A majority of the members



1 present and serving are required for official action of the
2 council.

3 (10) The council shall conduct its business in compliance with
4 the open meetings act, 1976 PA 267, MCL 15.261 to 15.275.

5 (11) A writing that is prepared, owned, used, possessed, or
6 retained by the council in performing an official function is
7 subject to the freedom of information act, 1976 PA 442, MCL 15.231
8 to 15.246.

9 (12) A member of the council is not entitled to compensation
10 for service on the council, but the council may reimburse a member
11 for actual and necessary expenses incurred in serving.

12 (13) At any time, the council may make recommendations to the
13 director on the appointment of additional members to the council
14 that the council considers necessary to carry out its duties.

15 (14) As used in this section and section 5135a:

16 (a) "Council" means the rare disease advisory council created
17 in subsection (1).

18 (b) "Rare disease" means a disease that affects fewer than
19 200,000 individuals in the United States.

20 Sec. 5135a. (1) The council may do 1 or more of the following:

21 (a) Apply for and accept grants and gifts from government and
22 private sources. The department shall provide clerical and
23 administrative assistance to the council in applying for grants
24 under this subdivision, as the director considers necessary or
25 appropriate.

26 (b) Hold public hearings and make inquiries and receive
27 comments from the general public to assist the council in
28 developing recommendations under this section.

29 (c) Consult with experts on rare diseases to assist the



1 council in developing recommendations under this section,
2 including, but not limited to, experts from the private sector,
3 organized labor groups, government agencies, and institutions of
4 higher education.

5 (2) The council shall do all of the following:

6 (a) Research and identify priorities relating to the cost-
7 effectiveness of and access to treatments and services provided to
8 individuals with rare diseases in this state, and develop policy
9 recommendations aimed at preventing discrimination against
10 individuals with rare diseases with respect to the cost-
11 effectiveness of and access to treatments and services and other
12 related issues.

13 (b) Identify best practices for rare diseases from other
14 states and at the national level that could improve the education,
15 care, and treatment of, and services and supports provided to,
16 adults and minors with rare diseases in this state.

17 (c) Coordinate with other rare disease advisory bodies,
18 community-based organizations, and other public and private
19 organizations in performing its duties under this section to ensure
20 greater cooperation between this state, other states, and the
21 federal government regarding the research, diagnosis, and treatment
22 of rare diseases, by disseminating the council's research,
23 findings, and recommendations when appropriate.

24 (d) Serve as an advisory body on rare diseases to the
25 legislature, the governor, the department, and other state
26 agencies.

27 (e) Research and make recommendations to the legislature and
28 the department on the most appropriate method to collect data on
29 rare diseases.



1 (f) Provide information or advice on rare diseases to the
2 department or governor, as the director or governor considers
3 necessary or appropriate.

4 (g) By December 21, 2022, develop a list of rare diseases and
5 post the list on the department's website. The council shall review
6 and update the list described in this subdivision every 2 years and
7 post the updated list on the department's website.

8 (h) Annually select 1 rare disease from the list described in
9 subdivision (g), investigate the rare disease, and make
10 recommendations to the legislature on the rare disease.

11 (i) Beginning December 21, 2022, and by December 21 of every
12 other year beginning after the first report is submitted to the
13 legislature under this subdivision, submit a written report to the
14 legislature on the activities, findings, and recommendations of the
15 council.

16 (3) Any findings and recommendations made by the council under
17 this section must be based on medical or scientific evidence.

18 Enacting section 1. This amendatory act takes effect 90 days
19 after the date it is enacted into law.

